ICCBBA

ISBT 128 Standard for Traceability

ISBT 128
For Cellular Therapy

An Introduction

17th Edition – 2025

IN-005

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1 Preface

Essential important information is presented on the label of a cellular therapy product. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the blood groups, expiration date, and product description are clearly understood by medical personnel transfusing or transplanting the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

This need for accurate transfer of information goes beyond borders. Cellular therapy (CT) products collected in one country or region may be used in another. This creates a need for international agreement on product descriptions and a means of ensuring globally unique identification of the donation to support traceability requirements. These fundamental requirements are essential for effective traceability on a global scale.

Cellular therapy establishments frequently operate sophisticated computer systems to enhance safety and efficiency. Transfer of information between such facilities by electronic means ensures accuracy but can only be effectively achieved in a global context by use of internationally agreed standards to define the information environment.

This is a high-level introduction to the ISBT 128 Standard. The Standard and additional information is available at www.iccbba.org.

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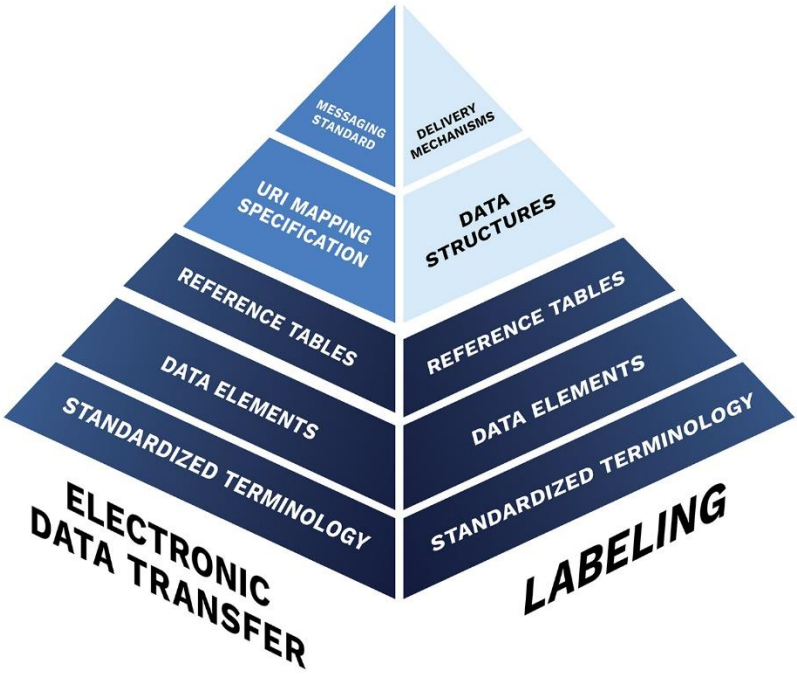
2 The Information Environment

The information environment model describes how ISBT 128 organizes information to achieve standardization for both labeling and electronic messaging for medical products of human origin (MPHO).

The foundation of the information environment contains standardized terminology, data elements, and reference tables. These layers support the structures, mechanisms, specifications, and standards necessary to print labels and create electronic messages. These layers are illustrated and described below.



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Standardized Terminology

Standardized terminology forms the base of the model. *ISBT 128 Standard Terminology for Medical Products of Human Origin* (ST-002) details a common understanding of terms. Without clarity at this level, any further attempt at standardization is futile. Obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus. For example, different concentrations of DMSO may be used during the cellular therapy cryopreservation process.

A range of standardized terminology and associated values are required to accommodate these variations. Collaboration with experts from around the world is necessary to ensure that internationally standardized terminology is defined at the required level of granularity. This provides confidence in the consistency of both the information being transferred and the quality of the product described. The standardized terminology is accessible to all users of the ISBT 128 Standard.

Data Elements

Data elements are discrete pieces of information, common to both labeling and electronic data transfer. Examples of data elements include product description codes, expiration dates, and division identifiers. Detailed descriptions are provided in *ISBT 128 Dictionary of Standard Data Elements* (ST-027).

Reference Tables

Reference tables convert the clearly defined information into codes suitable for transmission via either delivery mechanisms on labels or electronic data transfer. These tables are built to map each item to a suitable coding. Reference tables can be large and complex, and they must be managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner that maintains their integrity and avoids ambiguity or redundancy and retain backward compatibility.

Successful management of standardized terminology, data elements, and reference tables requires input from both clinical experts in the field and information specialists. The tables themselves need to be published in a manner that allows all users of the Standard to access the most up-to-date versions.

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Data Structures

Data structures define the technical characteristics necessary for the interpretation of the information on a label. They specify the context and structure and provide links to the appropriate reference tables for conversion of embedded codes to meaningful information. Data structures may contain more than one data element.

Data structures need to be unambiguous and consider any constraints imposed by the anticipated delivery mechanisms. Each ISBT 128 data structure is identified by and encoded with a distinct data identifier. All ISBT 128 data structures are defined in *ISBT 128 Standard Technical Specification* (ST-001).

Delivery Mechanism

The delivery mechanism is the means of delivering electronic information. The linear bar code has been used in blood transfusion practice for many years. There are several types of linear bar codes, including Code 128, a bar code standard widely used in coding standards such as GS1 and ISBT 128.

A range of delivery systems can sit at this level of the hierarchy. The standardized terminology, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in 2-dimensional data matrix symbol or an RFID tag. The standards themselves need to be adaptable to make best use of new delivery mechanisms as they are developed.

Labeling

The layers of the information environment described above support the labeling of CT products. Although some labeling requirements fall outside the information environment described in this document, an effective system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, a mechanism is needed to ensure correct physical assignment of information to the product and confidence in the association between electronically stored information and eye-readable printed information. This latter requirement must not be overlooked in the enthusiasm to embrace remotely re-writable tags.

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URI Mapping Specifications

For electronic data transfer, ISBT 128 data elements are identified by a uniform resource identifier (URI) in the form of a uniform resource locator (URL). This URL references a page on the ICCBBA website that carries the data element definition.

Messaging Standard

Messaging Standards define the rules for how systems exchange information. The ISBT 128 Standard can be used with multiple messaging standards, including but not limited to XML (Extensible Markup Language) and JSON (JavaScript Object Notation).

Electronic Data Exchange

The layers of the information environment described above support the transfer of MPHO information via electronic data exchange.

The Information Environment

Together, these elements form the information environment. For such a system to be and to remain effective, it must be carefully designed and managed. An on-going dialogue between clinical users, information specialists, and equipment and software vendors is critical to ensure that the standard continues to support rapidly developing clinical practice. ICCBBA routinely meets with a wide range of external experts via the ICCBBA Technical Advisory Groups and active collaboration with external organizations.

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3 Application of the ISBT 128 Standard

The ISBT 128 Standard provides the specification for many of the elements of the information environment required in transfusion and transplantation. It defines the standardized terminology, data elements, reference tables, data structures, and URI mapping specifications. Minimum requirements are also defined for delivery mechanisms, labeling, and electronic data transfer. By complying with the ISBT 128, Standard, collection and processing facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

- the fundamental elements of traceability;
    - a donation numbering system that ensures globally unique identification
    - standardized product description codes
    - division identification
    - processing facility identification
- the information to be transferred, using internationally agreed reference tables;
- an international product reference database;
- the data structures in which this information is placed;
- a bar coding system for transfer of the information on the product label;
- a standard layout for the product labels of some subject areas;
- a standard reference for use in electronic messaging.

The standard, originally accepted by the ISBT Council in 1994, has gained widespread acceptance. It has been extended beyond blood transfusion to include cellular therapy and all MPHO. More than 6,000 facilities across six continents are registered to use ISBT 128, and this number continues to grow. Millions of blood, cell, and tissue products are labeled with ISBT 128 each year.

The ISBT 128 Standard is endorsed by the boards of major cellular therapy professional organizations, including FACT, JACIE, and AABB. *Third Consensus Statement of Terminology, Coding and Labeling of Cellular Therapy Products* (JP-005).

The most current version of the standard terminology is maintained on the ICCBBA website at www.iccbba.org.

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4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation event worldwide. It does this by using a 13-character identifier built from three elements; the first element identifies the facility that assigned the number, (e.g., the collection facility, registry, etc.), the second the year, and the third a sequence number for the donation. For example:

S0020 23 001021 F

Where:

S0020 is the **F**acility **I**dentification **N**umber (FIN) of the facility that assigned the DIN (in this case Karolinska University Hospital, Stockholm, Sweden);

23 identifies the year in which the DIN was assigned;

001021 is the 6-digit sequence number controlled and maintained by the facility assigning the DIN.

These 13-characters comprise the **D**onation **I**dentification **N**umber (DIN).

The two digits printed vertically (the "flag" characters) allow individual bar codes in a number set to be discretely identified, providing an option to add process control into the collection and production processes.

An additional character is enclosed in a box at the end of the identifier. This is a checksum character used when a number is entered into a computer system through the keyboard to verify the accuracy of the keyboard entry. More information about the DIN can be found in the *ISBT 128 Standard Technical Specification* (ST-001).

FINs are assigned by ICCBBA, who maintains a database of all registered facilities on its website (www.iccbba.org). A lookup program allows the look up of individual facility codes. ICCBBA-licensed facilities and vendors are able to download a full listing of all registered facilities.

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5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product description codes (PDCs). The foundation of this system is a standard terminology which is constructed by international consensus to ensure global consistency in use and understanding. The standard terminology is maintained on the ICCBBA website and is publicly available. Cellular therapy terminology and coding is managed by ICCBBA and the international Cellular Therapy Coding and Labeling Advisory Group (CTCLAG).

Following the standardization of cellular therapy product labeling using ISBT 128, it has been recognized that there is a need to uniquely identify Clinical Trials products using the ISBT 128 Standard. To accommodate this need, rather than assigning a wide range of terminology to describe these products, the CTCLAG approved a new category of PDCs specifically for clinical trials. These clinical trials PDCs are allocated by ICCBBA and maintained within the Clinical Trials PDC database separately from globally standardized PDCs. More information can be found in *ISBT 128 Standard Use of Clinical Trials Product Description Codes* (ST-022).

New products are defined by combining pieces of information from the standardized terminology in a way that unambiguously describes the product. This process is made easier by the use of the concepts of component class, core conditions, and attributes.

This unique product description is assigned a Product Description Code that becomes incorporated into the ISBT 128 Product Description Code Database, ensuring that the product will be accurately identified in any country in the world that is using ISBT 128.

New entries into the Product Description Code Database can be readily accommodated, allowing the system to expand to meet a growing range of products without losing the overall structure of the coding system.

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The following example is taken from the database:

Component Class:	HPC, CORD BLOOD
Core Conditions:	NS (anticoagulant not specified)
	XX (variable volume)
	<=-150C (storage condition)
Attributes:	10% DMSO
	Other Additives:Yes
	Cryopreserved

Product Description Code: S1150

While the description of a product in the Product Description Code Database is standardized, the text that appears on the actual label of a product is under national control. This allows for differences in languages and regulatory requirements.

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6 Other Data Structures

In addition to the donation identifier and product identifier, many other pieces of important information need to be provided with a CT product. These vary by the type of product being labeled, as well as by national requirements. The ISBT 128 Standard provides over thirty data structures that can be used to code product information such as:

- ABO and RhD Blood Groups
- Chain of Identity Identification
- CMV and other test results
- Collection Container Catalog and Lot Number
- Collection Date and Time
- Division Identification
- Donor Identification Number
- Expiration Date and Time
- Flexible Date and Time (supporting encoding of local time, or UTC)

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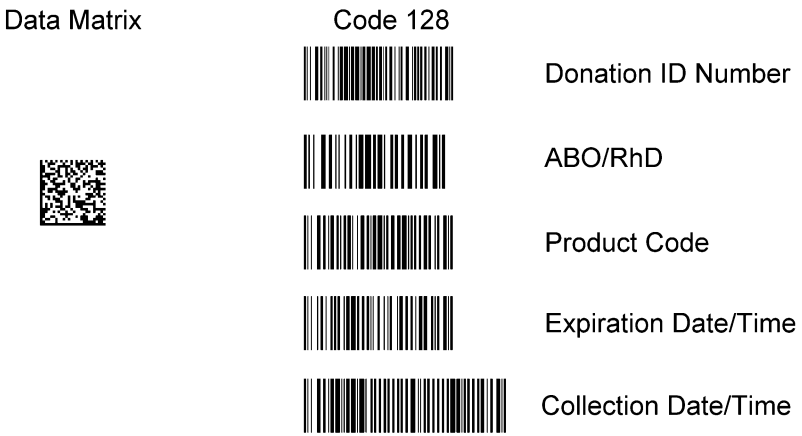
7 Delivery Mechanisms

The delivery mechanism is how the information is represented in a machine-readable manner. ISBT 128 has traditionally been based on the linear bar code using Code 128 symbology. However, a two-dimensional Data Matrix symbol can be used on cellular therapy labels and is preferable to maximize space on a partial or small label.

A single Data Matrix symbol can carry the same information as encoded in multiple linear bar codes. This allows more rapid scanning of CT products at the point of processing, distribution, and receipt. With very small containers, label size is severely restricted, and in these situations, a more efficient two-dimensional Data Matrix symbol can be used.

Figure 1 Comparative Size of Code 128 and Data Matrix Symbols



The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

To use Data Matrix, or other high efficiency delivery mechanisms, ISBT 128 data structures must be strung together in a standardized way into a single message called a Compound Message. More information on Compound Messages may be found in the *ISBT 128 Standard Technical Specification* (ST-001).

RFID tag technology may provide significant benefits in some situations. ISBT 128 Compound Messages are compatible with RFID.

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8 Product Labeling

In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on product labels. Critical eye-readable information such as blood groups, product description, and expiration date also appears in fixed positions on the label. This reduces the risk of confusion when products from multiple sources are being used.

When space is not an issue, the four-quadrant label has been defined for cellular therapy.

The ISBT 128-specified cellular therapy label is illustrated below. Additional label examples and further information may be found in *ISBT 128 Standard Labeling of Cellular Therapy Products* (ST-004).

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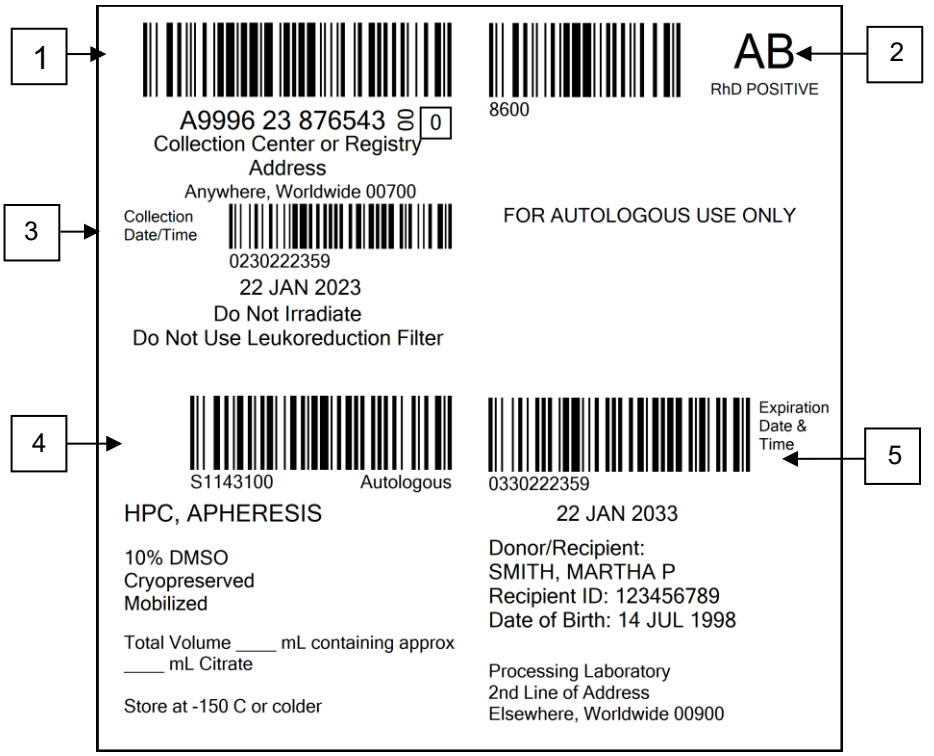
Figure 2 100 mm by 100 mm Cellular Therapy Label



1 Donation Identification Number
2 ABO/RhD
3 Collection Date/Time
4 Product Code
5 Expiration Date/Time

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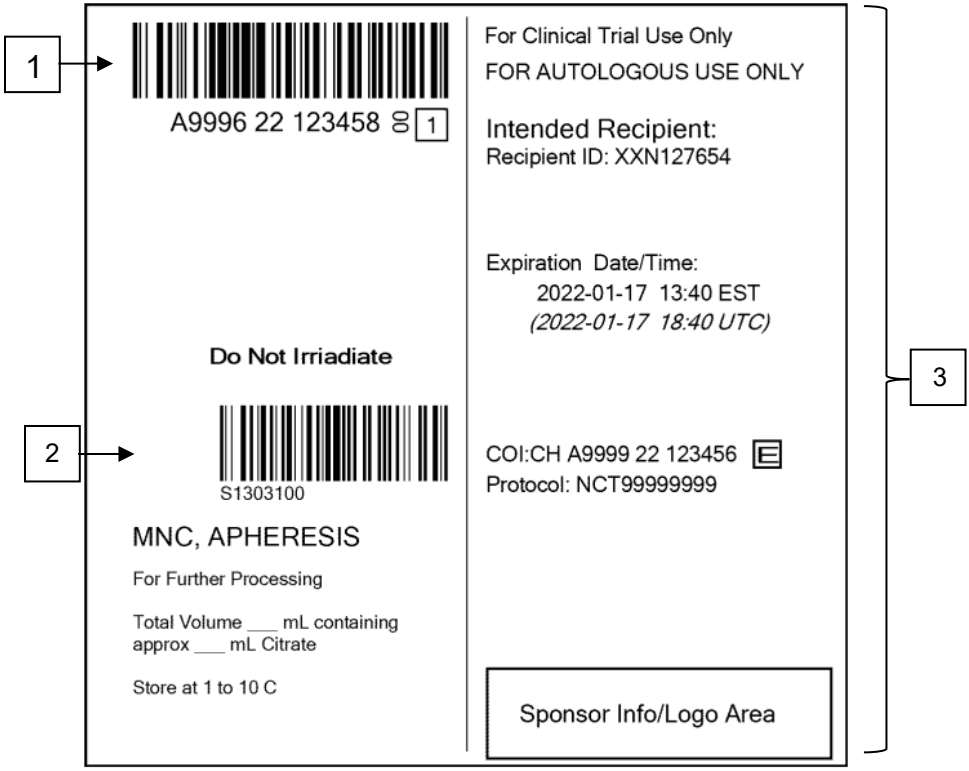
Products collected with the intent for further manufacture follow a labeling format similar to the ISBT 128 labeled products intended for transfusion and is illustrated below. This labeling format provides ISBT 128 traceability information on the left side of the label and manufacturer supplied information on the right side of the label. This hybrid-label format is detailed within *ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing* (ST-018). Specifications for the structure of the ISBT 128 CoI identifier can be found within *ISBT 128 Standard Chain of Identity (CoI) Identifier* (ST-028)

Figure 3 100 mm by 100 mm Hybrid Label for Collection Products for Cellular Therapy Manufacturing



1 Donation Identification Number
2 Product Code
3 Manufacturer Provided information

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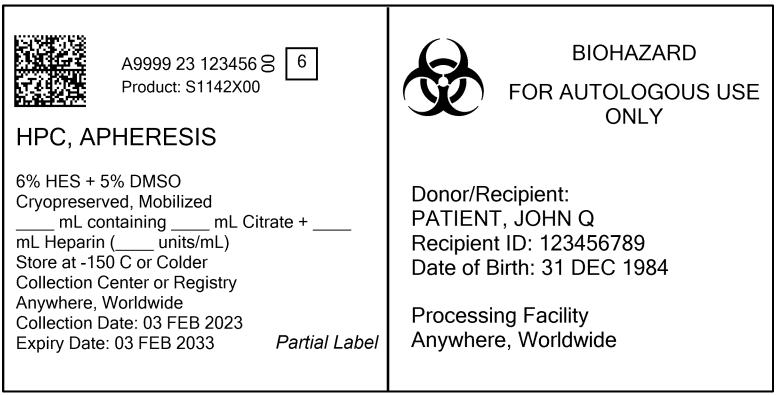
Labels have also been designed for smaller containers, such as cryopreservation container labels. The example shown below uses a 2-D Data Matrix symbol in the upper left corner to record the Donation Identification Number, Product Code, Expiration Date, Collection Date, Patient Identification Number (Patient ID), and Patient Date of Birth.

Figure 4 Cellular Therapy label for smaller container



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9 ISBT 128 and the Single European Code (SEC)

The SEC is a single European coding system that provides information on the main characteristics and properties of tissues and cells that fall under Directive 2004/23/EC and subsequently Regulation (EU) 2024/1938 of the European Parliament and of the Council. This directive applies to tissue and cell products released for circulation in the European Union unless specifically excluded in the regulation. It does not apply to products regulated under advanced therapy medicinal product regulations.

The implementing directive for the SEC is Commission Directive (EU) 2015/565. This directive further defines what elements comprise the SEC. Legislation requiring Tissue Establishments to apply the SEC took effect 29 April 2017.

ISBT 128 is a voluntary standard in most countries, although it is mandated in some EU Member States. To comply with the SEC Directive, facilities that are currently using ISBT 128 can utilize data that is already bar coded to derive much of the required content.

To help in creating the SEC for products labeled with ISBT 128, ICCBBA has developed a tool that is now available on the ICCBBA website. The easy-to-use interface asks users to input specific product and Tissue Establishment information and will generate the eye-readable SEC as well as the required barcode content.

For organizations responsible for clinical application, ICCBBA has created a data structure that will allow the encoded SEC to be automatically captured.

For facilities not yet using ISBT 128, implementation of both SEC and ISBT 128 simultaneously would save both time and effort. Many changes required for the SEC will involve similar process steps to the implementation of ISBT 128.

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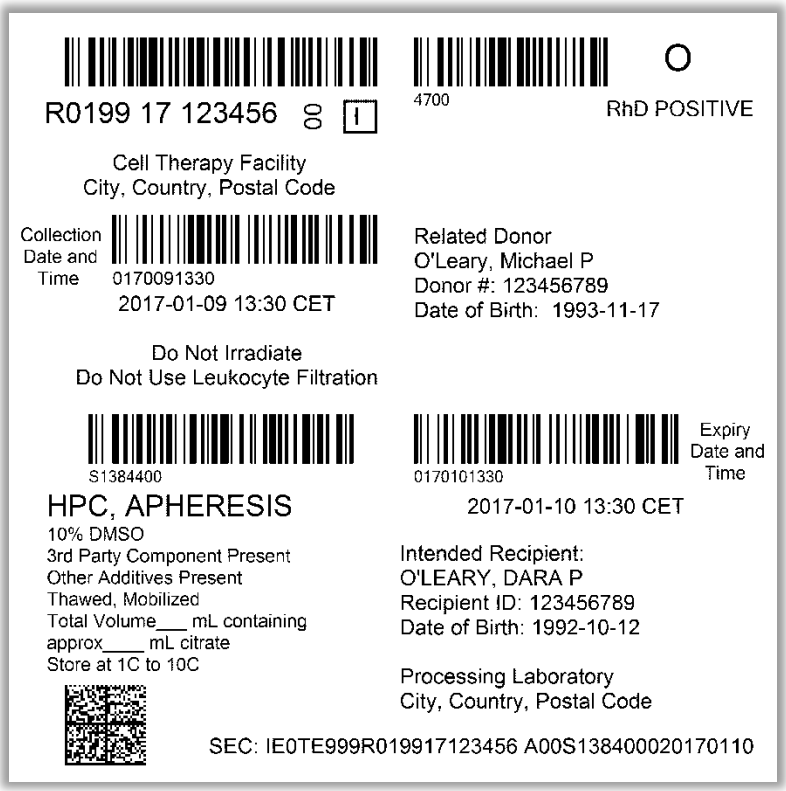
Figure 5 Cellular Therapy Label with Electronically Readable SEC



Note: The 2-D symbol in this example includes only the SEC.

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10 The Role of Technical Advisory Groups

ICCBBA involves international experts in various MPHO fields (e.g., blood, tissue, cellular therapy, regenerative medicine, medically assisted reproduction, and milk banking) in the development and maintenance of the ISBT 128 Standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly through asynchronous discussion forms, virtual meetings, and face-to-face meetings to further develop and expand the Standard, ensuring it continues to meet the needs of its users. The vital role of these groups cannot be overemphasized. It is only through the involvement of such expert panels that ICCBBA can be assured it has the knowledge base to anticipate the needs of its users in fields where change is constant. Hundreds of experts participate in the ICCBBA TAGs.

The technical advisory group for cellular therapy is the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG).

This international group includes representatives from professional organizations, technical experts, regulatory liaisons, and observers.

CTCLAG reviews requests for new terminology, ensuring consistency and consensus in terminology, prepares educational materials, and assists ICCBBA with organization of workshops by providing expertise from the cellular therapy community so that ICCBBA can better aid ISBT 128 users around the world.

The Standards Committee is comprised of TAG chairs and several Technical Experts. This committee reviews changes to the ISBT 128 Standard.

Additional information about the Standards Committee and each TAG and their activities can be found on the ICCBBA website (www.iccbba.org).

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11 The Role of ICCBBA

ICCBBA is the not-for-profit, nongovernmental standards body responsible for the management, development, and distribution of the ISBT 128 Standard. It maintains a staff to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports Technical Advisory Groups that include experts from both the transfusion/transplantation community and relevant manufacturers of equipment or software that use ISBT 128.

Registration and license fees collected by ICCBBA from registered facilities are used to support these functions.

Through its activities, ICCBBA provides the management support essential to sustain standard coding in the complex environment of MPHO such as cellular therapy. In particular it delivers:

1) Stability – users can be confident in the stability of the Standard to satisfy the long time periods over which information has to be retained (e.g. European Commission requirements for data to be stored and traceable for 30 years);
2) User focus – the user communities are the experts in their fields and ICCBBA, through its Technical Advisory Groups, ensures that the information standard meets, rather than dictates, user needs;
3) Flexibility – as clinical and scientific knowledge grows, there is rapid development with changing information needs. ICCBBA ensures that the Standard is flexible enough to accommodate those needs;
4) Responsiveness – in these rapidly developing medical fields, ICCBBA ensures that the Standard can respond to user needs in a timely manner;
5) Globalization – ISBT 128 is an international standard with endorsement worldwide;
6) Compatibility – standards do not work in isolation but need to interface with equipment, software, and other standards. ICCBBA works with industry and other standards bodies to maximize compatibility and interoperability (e.g., the Single European Code).

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Blood, cellular therapy, tissue, organ, banked human milk collection and processing facilities, and manufacturers of equipment or software that uses ISBT 128, are required to register with ICCBBA and pay a registration and an annual licensing fee. Registered organizations obtain access to all ICCBBA documents and databases.

For further information on ISBT 128, visit the ICCBBA website at www.iccbba.org, or contact our help desk at support@isbt128.org.

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12 ISBT 128 Implementation Resources

Multiple resources are available to assist users on their implementation journey, whether they are beginning to plan their initial implementation or planning to maximize the benefits of new features of the Standard.

All ISBT 128 Standards and Implementation Guides are available to the public on our website. The material is copyrighted, and registration is required for organizations to utilize the Standard.

Guidance on planning implementation is available in *ISBT 128 Implementation Toolbox* (IG-047). Valid and invalid data structures to assist users in performing validation activities are available in *Implementation Guide: A Validation Tool for ISBT 128 Data Structures* (IG-043).

The website provides registered users with access to multiple lookup tools, including product code and vendor lookup.

The ICCBBA helpdesk is available to both current and potential users. The team can provide answers to questions, review labels, and facilitate one-on-one consultations as needed. Users are advised to consult regulatory authorities in their own countries for information regarding regulations and authorities from voluntary accrediting organizations for information concerning standards other than ISBT 128. Regulatory requirements supersede the requirements of the ISBT 128 Standard.

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ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin
ST-004 ISBT 128 Standard Labeling of Cellular Therapy Products
ST-012 ISBT 128 and the Single European Code (SEC)
ST-018 ISBT 128 Standard Labeling of Collection Products for Cellular Therapy Manufacturing
ST-020 ISBT 128 Standard for XML
ST-022 ISBT 128 Standard Use of Clinical Trials Product Description Codes (PDCs)
ST-026 ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier
ST-027 ISBT 128 Dictionary of Standard Data Elements
ST-028 ISBT 128 Standard Chain of Identity Identifier

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