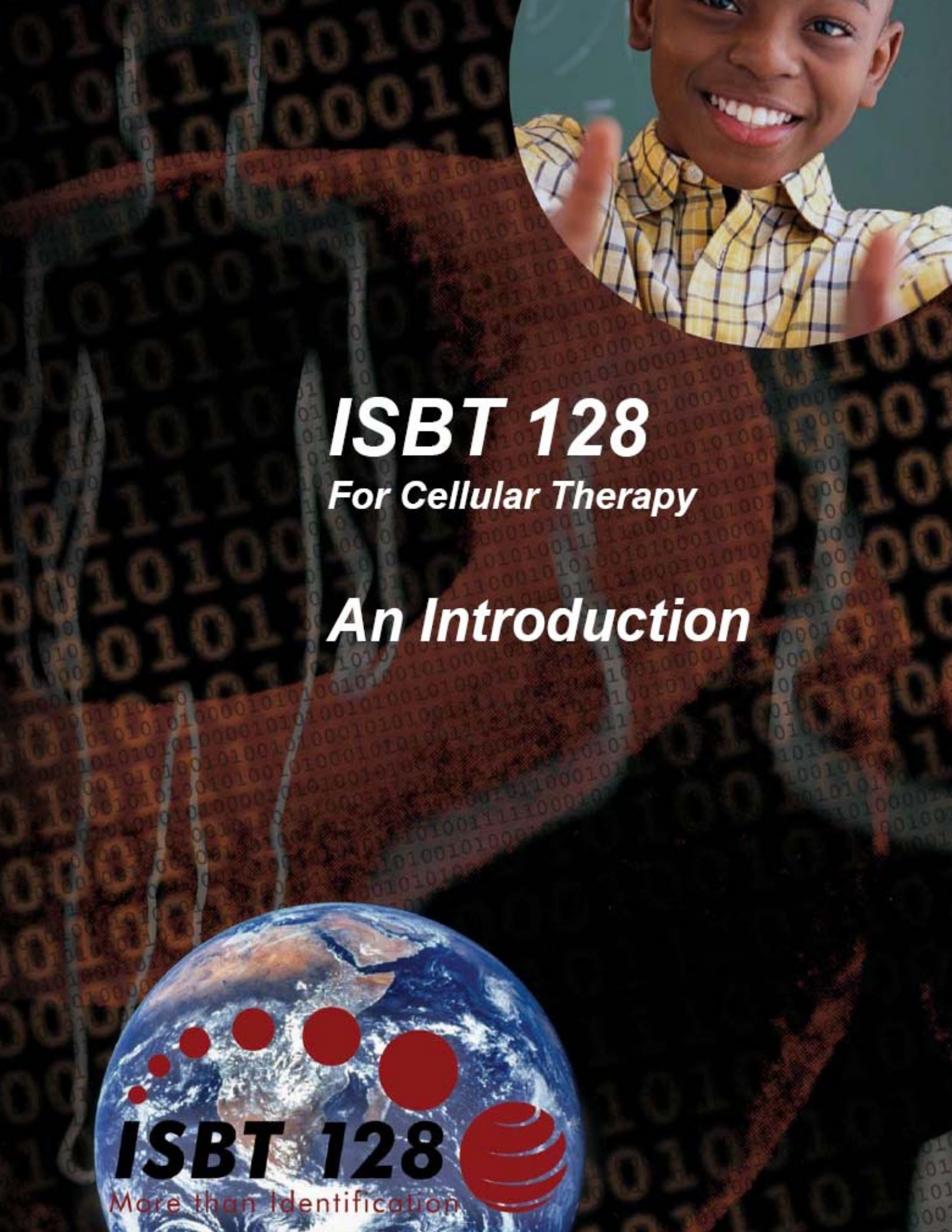

ISBT 128

For Cellular Therapy

An Introduction

ISBT 128

More than Identification

ISBT 128
For Cellular Therapy

An Introduction

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1 Preface

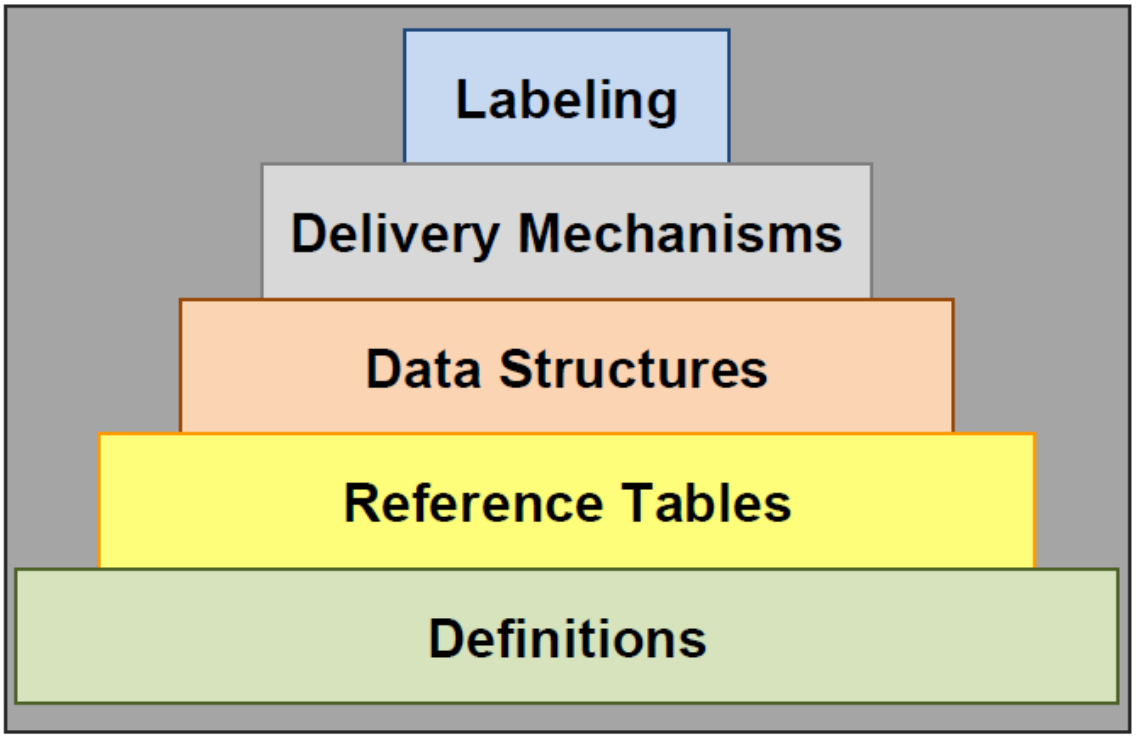
A great deal of important information is presented on the label of a cellular therapy product. The information varies from country to country according to licensing regulations, language differences, and local practice but, in all cases, it is essential that it is recorded accurately, transferred correctly, and that critical items such as the blood group, 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.

The field of Cellular Therapy (CT) is very much a global one and CT products are regularly transferred across national boundaries. There is a clearly identified need for international agreement on product descriptions and a means of ensuring a unique identification of the donation throughout the world. These fundamental requirements underpin the infrastructure required to provide effective traceability.

Increasingly, facilities dealing with the collection and administration of CT products 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.

2 What is the Information Environment?

The information environment comprises a number of layers each of which needs to be in place to ensure that standardization can be achieved.



Definitions

At the base lies the dictionary of definitions that will ensure common understanding of terms. Without clarity at this level any further attempt at standardization is lost. However, obtaining agreement on definitions at the necessary level of detail involves careful analysis and robust consensus. A simple example serves to illustrate this. DMSO is used during cryopreservation of a cellular therapy product. However, different concentrations may be used and hydroxyethyl starch may be added. In order to accommodate these variations a range of definitions and associated values are required. Extreme care is needed in order to ensure that an internationally agreed dictionary 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 dictionary of definitions needs to be accessible to all users of the standard.

Reference Tables

Once the definitions are in place, these can be combined to give the required items of information. Reference tables are built to map each item to a suitable coding. Such tables can be large and complex and it is essential that they are managed to ensure that they can be modified to meet the changing needs of clinical practice in a manner which maintains their integrity and avoids ambiguity or redundancy.

Product reference tables in particular need to combine a tightly defined structure with the flexibility to accommodate expansion and change in ways which cannot be anticipated.

Successful management of definitions 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 in a timely manner.

Data Structures

Having built reference tables which convert the clearly defined information into codes suitable for electronic transmission, it is necessary to define data structures in which to embed the data. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate reference tables for conversion of codes to meaningful information.
Data structures need to be clear and unambiguous and must take into account any constraints imposed by the anticipated delivery mechanisms. For example, data structures that will be used in linear bar codes are limited in the number of characters they can contain.

Delivery Mechanism

The delivery mechanism is the means of delivering the electronic information. Probably the most well known delivery mechanism is the linear bar code that has been used in blood transfusion practice for many years. There are in fact several types of linear bar codes including the old fashioned Codabar system that was only capable of encoding numeric information, and Code 128, a bar code standard widely used in coding standards such as GS1 and *ISBT 128*.

Higher capacity delivery systems are available using 2-dimensional or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently we are seeing the development of radio frequency identification (RFID) chips which can carry encoded information.

It is important to recognize that a range of delivery systems can sit at this level of the hierarchy. The definitions, reference tables, and data structures of the information standard can be delivered as easily in a linear bar code as they can in an RFID tag. The standards themselves need to be adaptable in order to make best use of new delivery mechanisms as they are developed.

Labeling

The final element in the Coding System is the associated labeling. Although there will be other labeling requirements that fall outside the coding system, an effective coding system needs to consider the physical association between the information and the product. Whether incorporated into a bar code or an electronic tag, there needs to be a mechanism that will 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.

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. There must be an ongoing dialogue between clinical users, information specialists and equipment and software vendors to ensure that the standard continues to support rapidly developing clinical practice.

3 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 lower three levels of the model, the definitions, reference tables, and data structures. Minimum requirements are also defined for delivery mechanisms and labeling. By complying with *ISBT 128*, collection and processing facilities can provide electronically readable information that can be read by any other compliant system.

ISBT 128 specifies:

- a donation numbering system that ensures globally unique 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 label;
- a standard reference for use in electronic messaging.

The standard, originally designed for use in blood transfusion, has gained international acceptance and is now in widespread use.

Following meetings between FACT, JACIE, and ICCBBA, an agreement was reached to standardize on the use of *ISBT 128* for coding and labeling CT products, and this decision has been endorsed by the Boards of major cellular therapy professional organizations.

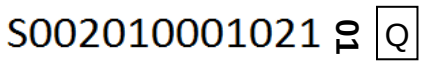
AABB, FACT, and JACIE now require the use of *ISBT 128* cellular therapy terminology in their accredited facilities.

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

While the description of a product in the product 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.

4 Unique Donation Identification

ISBT 128 provides for unique identification of any donation worldwide. It does this by using a 13-character identifier built up from three elements: the first identifying the collection facility (or registry), the second is the year, and the third is a sequence number for the donation. For example:



where:

S0020 identifies the collection facility (in this case Karolinska Universitets sjukhuset, Stockholm, Sweden);

10 identifies the collection year as 2010;

001021 is the sequence number of the donation assigned by the collection facility.

The two digits printed vertically allow individual bar codes in a number set to be discreetly identified hence providing an option to add process control into the collection process.

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.

Collection facility codes are assigned by ICCBBA, who maintains a database of all registered facilities on their Website (www.iccbba.org). A lookup program allows lookup of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all licensed facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning product codes. 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 is managed by the International Cellular Therapy Coding and Labeling Advisory Group

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

This unique product description is assigned a product code number that becomes incorporated into the *ISBT 128* product description database table, ensuring that the product will be accurately identified in any country in the world that is using *ISBT 128*.

New entries into the dictionary 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.

An example taken from the database tables is:

Component Class:	HPC, CORD BLOOD
Modifier:	Cryopreserved
Core Conditions:	Anticoagulant not specified;
	Volume not specified;
	Storage conditions: <=-150C
Attributes:	10% DMSO
	Other Additives:Yes

has product code S1150.

6 Other Data Structures

In addition to the donation identifier and product codes, many other pieces of important information need to be provided with a CT donation. *ISBT 128* provides a wide range of other data structures including:

- ABO and RhD Blood Groups;
- Collection Date and Time;
- Expiration Date and Time;
- HLA Typing Information;
- Collection Container Catalog and Lot Number;
- Donor Identification Number;
- Patient Date of Birth;
- Patient Identification Number.

7 Delivery Mechanisms

The delivery mechanism is the means by which the information is represented in a machine readable manner. The most common such mechanism is the linear bar code. *ISBT 128* has traditionally been based on the linear bar code using the Code 128 symbology and this is still used where space permits. With very small containers, label size is severely restricted and in these situations a more efficient two-dimensional Data Matrix symbol can be used. By using the *ISBT 128* Compound Message, many pieces of information can be combined into a single symbol that occupies a very small area.

Comparative Size of Code 128 and Data Matrix Symbols

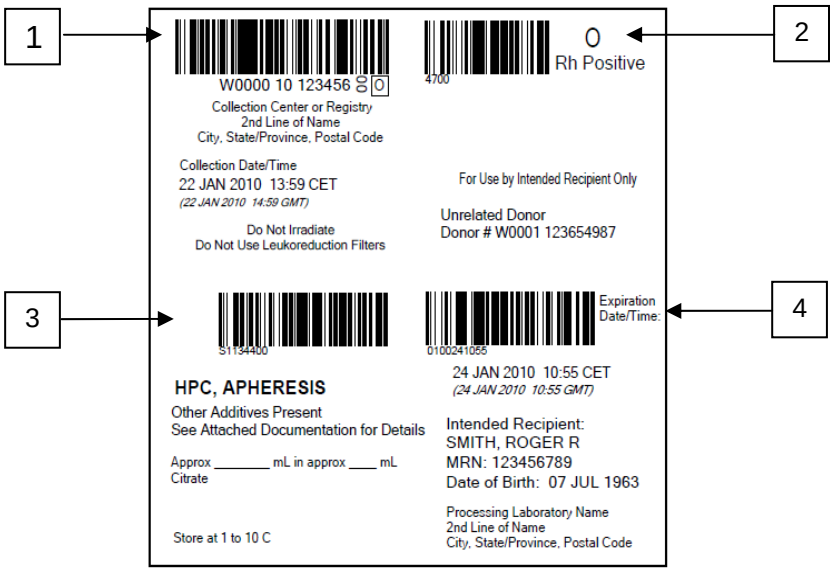
The Data Matrix symbol on the left contains all of the information held in the five Code 128 symbols on the right.

There is much interest in the use of RFID tags. This technology is still developing, but may provide significant benefits in some situations. *ISBT 128* Compound Messages are compatible with RFID.

8 Product Labeling

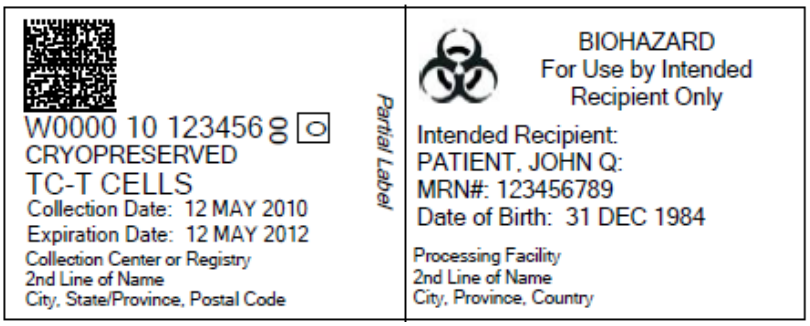
In addition to specifying the requirements for the electronic coding of information, *ISBT 128* provides a standard labeling format that ensures a consistent layout of product labels with the bar codes. Critical eye readable information such as blood groups, product description, and expiration date appear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

The *ISBT 128*-specified label is illustrated below. Additional label examples and further information may be found in *Product Code Structure and Labeling - Cellular Therapy Products.* This document may be found on the ICCBBA Website (www.iccbba.org).



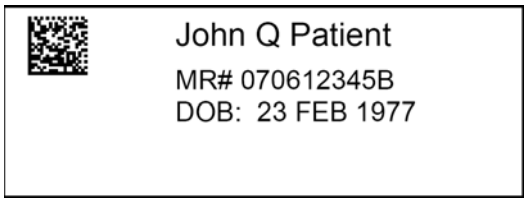
1 Donation Identification Number
2 ABO/RhD
3 Product Code
4 Expiration Date and Time

Labels have also been designed for smaller containers, such as cryopreservation container labels. The example shown uses a Data Matrix 2-D bar code in the upper left corner to record the donation identification number, product code, collection date, expiration date, patient date of birth, and patient medical record number (MRN).



9 Improving Safety at the Bedside

Misidentification at the bedside is recognized as one of the prime causes of errors. In order to support improved safety at this critical point, *ISBT 128* data structures have been developed to hold patient critical information including date of birth and hospital number. An important characteristic of these data structures is the use of a 'location code' which allows the reading system to identify the item from which a code was read; hence it is possible to electronically distinguish between a patient identifier scanned from a wrist band or from a cross match label. This permits a high degree of control over the verification process.



10 The Role of Technical Advisory Groups

ICCBBA involves international experts in blood, cellular therapy, and tissue banking in the development and maintenance of the standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (both face-to-face and through conference calls) 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. More than 150 experts participate in the ICCBBA TAGs.

For Cellular Therapy, this advisory group is the Cellular Therapy Coding and Labeling Advisory Group (CTCLAG). The group comprises representatives from the following professional organizations: AABB, Asia Pacific Blood and Marrow Transplant (APBMT), American Society for Blood and Marrow Transplantation (ASBMT), American Society for Apheresis (ASFA), European Group for Blood and Marrow Transplantation (EBMT), Foundation for the Accreditation of Cellular Therapy (FACT), ICCBBA, International Society of Blood Transfusion (ISBT), International Society for Cellular Therapy (ISCT), ISCT Europe, Joint Accreditation Committee of ISCT and EBMT (JACIE), National Marrow Donor Program (NMDP), and the World Marrow Donor Association (WMDA). In addition to these representatives, technical experts and regulatory liaisons also serve on the committee.

CTCLAG reviews requests for new terminology ensuring consistency and consensus in terminology, prepares educational materials, and organizes workshops for *ISBT 128* users around the world. The Standard that resulted from their work was published in July 2007 (Ashford, P, Distler, P, Gee, A, et al. Standards for the Terminology and Labeling of Cellular Therapy Products. Transfusion 2007;47:1319-27).

11 The Role of ICCBBA

ICCBBA is the not-for-profit standards body responsible for the management, development and distribution of the *ISBT 128* Standard. It maintains a permanent office to manage the registration of facilities, update reference tables and databases, and develop additional functionality. It supports technical advisory groups made up of experts from both the transfusion/transplantation community and relevant manufacturers. 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 and rapidly changing field of 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. EC requirements for data to be stored and traceable for 30 years);
2) user focus – the user community are the experts in their field 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 these needs;
4) responsiveness – in these rapidly developing medical fields ICCBBA ensures that the standard is able to respond to user needs in a timely manner;
5) globalization – *ISBT 128* is a truly 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.

Blood, Cellular Therapy and Tissue collection facilities, and manufacturers of equipment or software that uses *ISBT 128*, are required to register with ICCBBA and pay a registration and an annual license 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.
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