ISBT 128
For Blood Components

An Introduction

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IN-003

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1 Preface

A great deal of important information is presented on the label of a blood 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 the product. In addition, robust audit trails must be in place to allow tracing between donor and recipient.

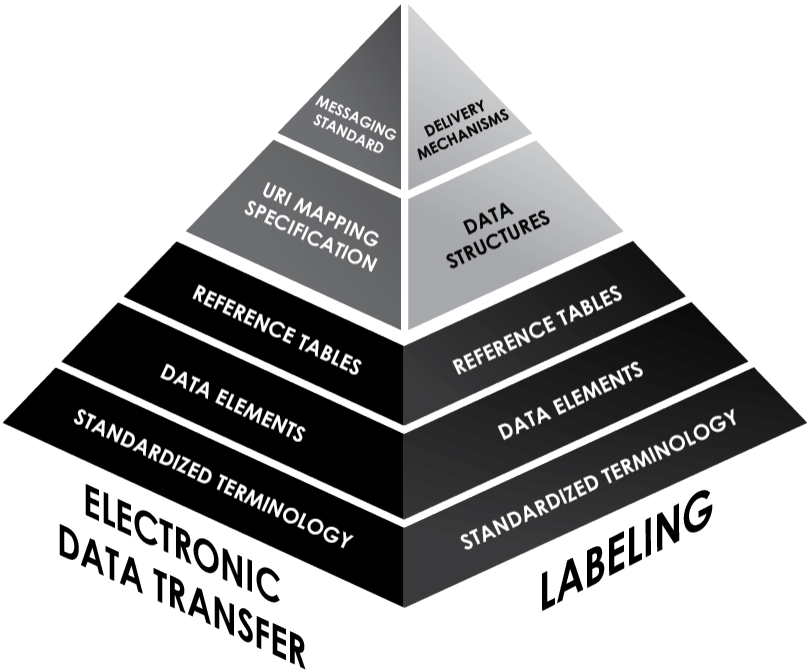
In today's world of multinational relief programs and military operations, blood products collected in one country may be used in another. There is a clearly identified need for ensuring the unique identification of the donation throughout the world and for international agreement on product descriptions. These fundamental requirements are essential for effective traceability on a global scale.

Increasingly, collection and transfusion facilities 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 the use of internationally agreed standards to define the information environment.

2 What is 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.



Standardized Terminology

At the base lies the standardized terminology, ISBT 128 Standard Terminology for Medical Products of Human Origin (ST-002), that will ensure a common understanding of terms. ISBT 128 Standard Terminology is the foundation used for both labeling and electronic messaging. Without clarity at this level any further attempt at standardization is lost. Obtaining agreement on standardized terminology at the necessary level of detail involves careful analysis and robust consensus.

ICCBBA ensures that an internationally agreed upon 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 Standard and ISBT 128 stakeholders.

There are terms regularly used in certain categories of MPHO that require an appropriate level of granularity to clearly convey the characteristics of the product. For blood products, the term 'leukodepleted' is routinely understood as meaning the removal of leukocytes from a blood component, however, there are different ways of carrying out such a removal, and differing amounts of residual leukocytes that are used to define *leukodepleted*. To accommodate these variations, a range of standardized terminology and associated values are required.

Data Elements

Product information and characteristics such as the Donation Identification Number, ABO RhD, and Product Description Code (PDC) constitute a data element. Data elements can be encoded within data structures suitable for use in bar codes applied to product labels, and they can also be identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL) for use in electronic messaging. Data elements provide a mechanism to unambiguously define pieces of information. The data elements are used to build data structures, and in some instances, more than one data element is needed to encode a data structure.

Example:
The Product Code data structure contains up to 3 data elements: the Product Description Code, the Collection Type, and the Division Identifier.

Reference Tables

Reference tables are built to code/decode a single or multiple data elements to provide data compression for use in a data structure. Such tables can be large and complex, and it is essential that they are managed to ensure that they can be modified to meet changes within clinical practices in a manner that maintains their integrity and avoids ambiguity or redundancy.

Reference tables combine a tightly defined structure while allowing the flexibility to accommodate expansion and change in ways that cannot be anticipated.

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

Together, the standardized terminology, data elements, and reference tables provide the basis for accurately relaying information about medical products of human origin, whether on the label or via electronic data transfer.

Electronic Data Transfer

URI Mapping Specification for use in Electronic Messaging

To support the transmission of ISBT 128 information via electronic messaging, ICCBBA has developed a dictionary of data elements, ISBT 128 Dictionary of Standard Data Elements (ST-027). The information carried in these elements maps to the same information carried in data structures to ensure that information from either source is consistent. Each data element is identified by a unique resource identifier (URI) in the form of a uniform resource locator (URL).

To view an example of a Product Description Code, go to https://www.isbt128.org/uri/ProductDescriptionCode.

Messaging Standard for use in Electronic Messaging

ISBT 128 provides specifications, ISBT 128 Standard for XML (ST-020), for use in electronic messages to convey information regarding MPHO in a consistent and standardized format.

The MPHO Unique Identifier is a single unique instance identifier developed to provide the basic elements of traceability. The MPHO Unique Identifier was developed to store traceability information on any MPHO and provides a single identifier for use in electronic messaging and electronic health records and should be used as the identifier element for the HL7 FHIR BiologicallyDerivedProduct resource.

This identifier can be created from a standard ISBT 128 label and clearly identifies the specific product being referenced in an electronic message. Specifications for the MPHO Unique Identifier are detailed in ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier (ST-026).

Electronic Messages

The development of a standardized approach to incorporate ISBT 128 Data Elements into electronic messages is an important step in improving the communication between healthcare organizations involved in the production and clinical application of MPHO. By adopting this Standard, organizations will be able to benefit from the MPHO-specific standardized terminology and standard reference tables of ISBT 128 in a wide range of contexts and securely transfer more information about MPHO products with far greater flexibility.

Labeling

Data Structures for use in Labeling

Having built reference tables which convert the clearly defined information into codes suitable for use in bar codes applied to product labels, 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 must be clear and unambiguous and consider 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.

Data identifiers indicate the type of information being conveyed within data structures. It is imperative that the appropriate data identifiers are used for each data structure to ensure the correct interpretation of the encoded information.

Delivery Mechanisms for use in Labeling

The delivery mechanism is the means of delivering the electronic information encoded within data structures. The most well-known delivery mechanism is the linear bar code that has been used in blood transfusion practice for many years.

Higher capacity delivery systems are available using Data Matrix two-dimensional (2-D) or reduced space symbology bar codes. These codes can carry much more information in each symbol. More recently the use of Radio Frequency Identification (RFID) chips that can carry encoded information is being developed for medical products of human origin.

It is important to recognize that 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 an RFID tag. The standards themselves must be adaptable to make the best use of new delivery mechanisms, such as Bluetooth Low Energy tags, as they are developed.

Information Environment Summary

Every ISBT 128-labeled product carries a standardized label where product information is encoded in bar codes or electronic tags. Although there will be other labeling requirements that fall outside the coding system, an effective coding system should 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 the 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 rewritable tags.

While highly effective and secure, labeling does have some limitations. In particular, the amount of information that can be encoded on the label depends on the amount of label space available to accommodate bar codes. Thus, as noted in previous sections, ISBT 128 has evolved to allow ISBT 128 information to be transmitted in electronic messages used in healthcare applications in a manner that is compatible with its existing labeling standards, giving the Standard the ability to overcome the limitations of bar codes.

The information environment works together to ensure that accurate ISBT 128 information is encoded within an electronic message or label to accurately identify MPHO products. 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 practices, ensures traceability, improves biovigilance efforts, and increases patient safety.

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 standardized terminology, 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 Standard specifies:

- a donation numbering system that ensures globally unique identification for a one-hundred-year period;
- 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 been expanded and developed over time to accommodate the adapting needs of various MPHO industries. This inherent elasticity of the Standard has led to its international acceptance and widespread use for labeling of MPHO products, with more than 40 million MPHO products labeled using ISBT 128 each year.

The most current version of the standard terminology is maintained on the ICCBBA website at www.isbt128.org.

4 Unique Donation Identification (DIN)

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, the second the year, and the third a sequence number for the donation. For example:

G1517 23 600001 10 x

Where:

G1517 identifies the collection facility (in this case Welsh Blood Service, Wales, United Kingdom);

23 identifies the year in which the Donation Identification Number was assigned (in this case 2023);

600001 is the serial number of the donation assigned by the collection facility.

The two digits printed vertically are flag characters that allow individual bar codes in a number set to be discretely identified providing an option to add process control.

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.

Facility codes are assigned by ICCBBA who maintains a database of all registered facilities that can be found on their website (www.isbt128.org). A lookup program on the website allows the look up of individual facility codes. ICCBBA licensed facilities and vendors are able to download a full listing of all registered facilities.

5 Product Descriptions

ISBT 128 provides a comprehensive and highly flexible system for describing products and assigning Product Description 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. Product description terminology is managed by the Technical Advisory Groups of ICCBBA.

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 components such as Classes, Modifiers, Core Conditions, and Attributes.

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

New entries into the ISBT 128 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.

The following example is taken from the database table: for PDC E0206:

- Component Class: Red Blood Cells
- Modifier: None
- Core Conditions: CPDA-1 (anticoagulant)
  - 450 mL (nominal collection volume)
  - Refrigerated (storage condition)
- Attribute: Irradiated
- E0206 = RED BLOOD CELLS|CPDA-1/450mL/refg|Irradiated

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.

6 Other Data Structures

In addition to the Donation Identification Number and Product Description Codes, many other pieces of important information need to be provided with a blood donation. Through its wide range of data structures, ISBT 128 provides significant information including, but not limited to:

- ABO and Rh(D) Blood Groups;
- Type of Collection (Volunteer, Directed, Autologous, *etc*);
- Expiration Date and Time;
- Collection Date and Time;
- Red Cell Phenotyping Information;
- HLA Typing Information;
- CMV and other test results;
- Collection Container Catalog and Lot 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 Code 128 symbology and this is still required on blood donations. However, an additional two-dimensional Data Matrix code may be added to a blood component label.

A single Data Matrix symbol can carry the same information as encoded in multiple linear codes. This allows much more rapid scanning of units at the point of blood center issue and receipt into the transfusion laboratory. In the cellular therapy and tissue banking fields, the need to use very small containers means that label size is severely restricted, and, in these situations, a Data Matrix symbol may replace linear codes.

Comparative size of Code 128 and Data Matrix Symbols

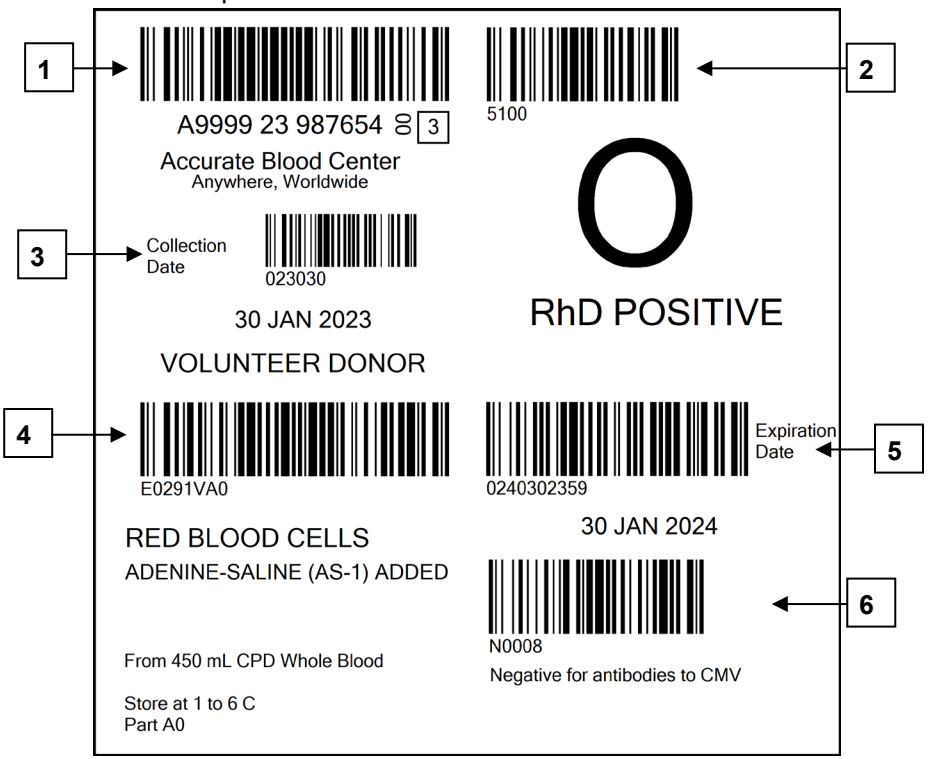
The Data Matrix symbol on the left contains all of the information held in the five Code 128 bar codes on the right.

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

8 Product Labeling

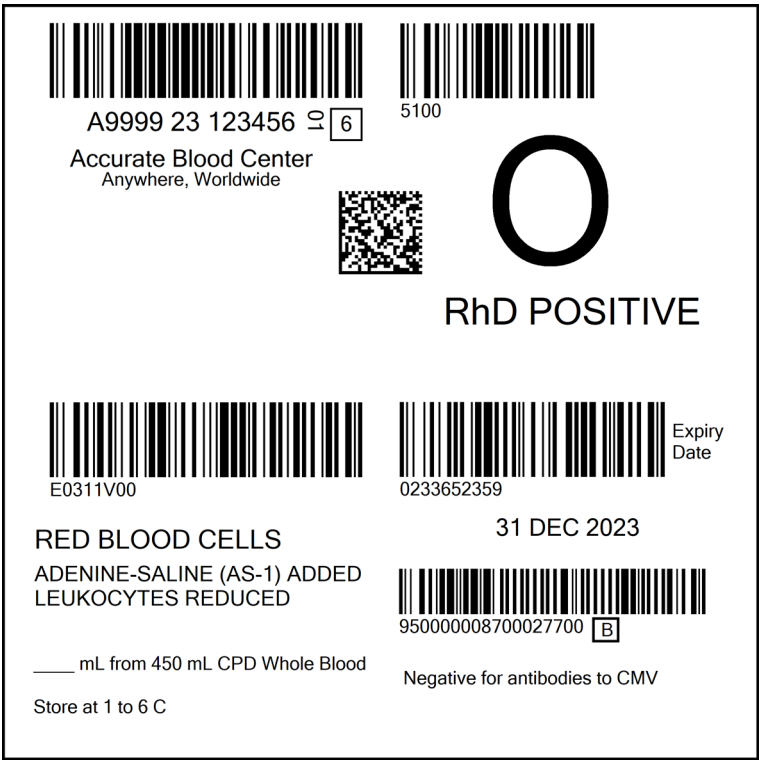
In addition to specifying the requirements for the electronic coding of information, ISBT 128 provides a standard labeling format that ensures a consistent layout of the bar codes on product labels. Critical eye-readable information such as blood groups, product description, and expiration date also 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.



1 Donation Identification Number
2 ABO/Rh Blood Groups
3 Collection Date (optional)
4 Product Code
5 Expiration Date (and Time)
6 Special Testing (optional)

In addition to linear bar codes, a 2-D data matrix symbol, comprising all the information in the linear bar codes, may be placed on the label. Scanning a single code improves efficiency but requires an imaging scanner.



9 The Role of Technical Advisory Groups

ICCBBA involves international volunteer experts in various MPHO fields to further develop and maintain the Standard. These experts are organized into Technical Advisory Groups (TAGs) that meet regularly (through conference calls, face-to face meetings, and asynchronous discussion forums) 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 300 experts participate in the ICCBBA TAGs.

For Blood Banking, the advisory groups are the Asia Pacific Technical Advisory Group (APTAG), the Europe, Middle East, and Africa Technical Advisory Group (EMATAG), and the Americas Technical Advisory Group (ATAG). The groups comprise participants from blood collection facilities, testing laboratories, transfusion services, professional organizations, regulatory agencies, and vendors from around the world.

10 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 that include 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 blood banking environment. 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;
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 those 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 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.

MPHO collection and processing facilities, and manufacturers of equipment or software that use 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.isbt128.org, email our helpdesk at support@isbt128.org, or call us at +1 909 793 6516.

END OF PUBLICATION

FOR ICCBBA USE ONLY

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

ST-002 ISBT 128 Standard Terminology for Medical Products of Human Origin

ST-020 ISBT 128 Standard for XML

ST-026 ISBT 128 Standard for the Medical Products of Human Origin (MPHO) Unique Identifier

ST-027 ISBT 128 Dictionary of Standard Data Elements

