IMPLEMENTATION GUIDE

Use of Data Matrix Symbols with ISBT 128

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Editor(s)

Pat Distler, MS, MT(ASCP)SBB
Technical Expert, ICCBBA

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1 Introduction

1.1 Purpose

The purpose of this document is to assist users and software developers to implement Data Matrix two-dimensional (2-D) symbology for delivery of ISBT 128 data structures for labeling of medical products of human origin (MPHO). Labeling includes affixed, attached, and accompanying labeling.

1.2 Scope

This document provides background information and examples of the use of Data Matrix with ISBT 128 data structures. It provides supplementary information only and is therefore intended to be used in conjunction with the *ISBT 128 Standard Technical Specification* (ST-001).

1.3 Intended Audience

This document is intended for staff (management, laboratory, quality, and information technology) of facilities using ISBT 128, software developers, and manufacturers of labels for MPHO.

1.4 Normative References

ISBT 128 Standard Technical Specification (ST-001)

ISO/IEC 16022:2006(E): Information technology—Automatic identification and data capture techniques -- Data Matrix bar code symbology specification

ISO/IEC 15415:2004 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Two-dimensional symbols

ISO/TS 18530:2014 Health Informatics—Automatic identification and data capture marking and labelling – Subject of care and individual provider identification

1.5 Other References

Palmer, RC. The bar code book. Victoria: Trafford Publishing, 2007.

Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations (IG-013)

Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010; 98(s2):1-24.

1.6 Background

Code 128 symbology for linear bar codes was selected as the delivery mechanism for ISBT 128 in 1989 because it offered a variety of desirable features including: it was alphanumeric; it was widely supported; and it provided high density, flexibility, and high data security. As the use of ISBT 128 expanded to tissues and cellular therapy products, and as the amount of information to be conveyed increased, it became necessary to evaluate delivery mechanisms that allowed more information to be encoded in a smaller

space. Both two-dimensional (2-D) symbols and Radio Frequency Identification (RFID) tags offered this capacity.

Information about the use of RFID is out of the scope of this document. Further information may be found in: Knels R, Davis R, Ashford P, et al: Guidelines for the use of RFID technology in transfusion medicine. Vox Sang 2010; 98(s2):1-24.

There are a number of 2-D symbologies available. Requirements for the selection of a 2-D symbology for ISBT 128 included:

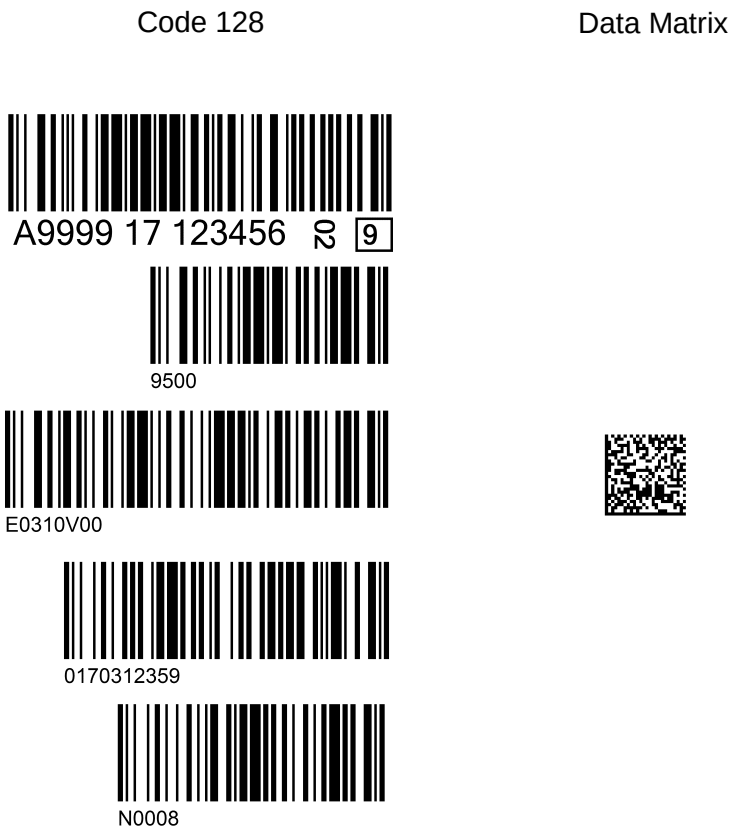
- It had to be capable of encoding up to 150 characters.
- It had to support the full set of characters supported by Code 128 (full US ASCII character set).
- The symbol had to fit on a space of 13 mm x 13 mm. (It was accepted that 2-D bar codes may not meet the requirements of small containers with even less space.)
- Reed-Solomon error-checking (or equivalent) mechanism had to be supported.
- Commonly available printers had to be able to print the symbols.

Reading technology (scanners) had to be:

- Cost-effective
- Commonly available
- Available as both handheld devices and fixed devices (found on automated testing equipment)
- Able to read both the selected 2-D symbol and Code 128
- Able to scan a variety of “challenging” surfaces:
    - Curved surfaces, such as a cylindrical vial 13 mm in diameter
    - Irregular surfaces (e.g., frozen product bag)
    - Wet or frosty surfaces (e.g., frozen product bag)

After a careful analysis, Data Matrix (ECC 200) was chosen as the required 2-D symbol for ISBT 128 label applications for MPHO. It is also recommended for non-label applications. Data Matrix was selected because it best met the criteria, especially the criterion of density. A 10 mm square Data Matrix symbol can encode as much information as five linear bar codes (see Figure 1, Page 8).

Figure 1 Comparison of the Size of Data Matrix and Code 128 Symbols



All information in the 5 linear bar codes on the left is also encoded in the 2-D symbol on the right.

1.7 New in this Version

	Chapter, Section or Table in Version 1.2.0	Chapter, Section or Table in Version 1.3.0	Change	Rationale
1.	Throughout	Throughout	Removed references to the use of ISBT 128 data structures on patient wristbands.	It is now recommended that facilities use the patient identification structure described in ISO/TS 18530:2014.
2.	New information	1.4	A reference to ISO/TS 18530:2014 was added.	This document describes a means of identifying patients that is recommended over ISBT 128 Data Structure 025.
3.	New information	2.3.1	Information for encoding a single data structure was added.	A single data structure may be encoded in a 2-D symbol.
4.	2.3	2.3.2	This section was reworded and the paragraph that discouraged the use of messages not specified by ICCBBA was deleted.	Previously this section described ICCBBA-specified messages as “structured” and non-ICCBBA-specified messages as “unstructured.” This is not correct; both types of messages are structured. The complexity created by multiple product categories, and the many codes that would result from permutations, made the use of ICCBBA-specified messages less practical.
5.	New information	2.4.4	Added a note that indicates ICCBBA now encourages use of undefined messages.	The complexity created by multiple product categories, and the many codes that would result from permutations, made the use of ICCBBA-specified messages less practical.

	Chapter, Section or Table in Version 1.2.0	Chapter, Section or Table in Version 1.3.0	Change	Rationale
6.	2.4	2.4	Changed the wording in the sections describing text.	This was done to improve clarity and for consistency with the *ISBT 128 Standard Technical Specification* (ST-001).
7.	2.4.5	2.4.4	Added a note about the placement of a 2-D symbol on a transition label for blood.	Placement of a 2-D symbol on a blood label is currently under discussion.
8.	New information	2.4.4	A sentence was added indicating that while linear bar codes are currently required on blood labels, this will not be true in the future.	An ICCBBA committee is designing a blood label with a 2-D symbol only.

2 Use of Data Matrix with ISBT 128

2.1 Specifications for the Use of Data Matrix with ISBT 128

2.1.1 General Requirements

Data Matrix (ECC 200) shall be used as the 2-D symbology for ISBT 128 sample and product labels. The ISO/IEC 16022:2006(E): Information technology—Automatic identification and data capture techniques -- Data Matrix bar code symbology specification shall be followed.

For applications of ISBT 128 other than sample or product labels, Data Matrix is recommended.

2.1.2 Symbol Quality

Using methodology described in ISO/IEC 15415, print quality shall be 1.5/6/670 where 1.5 is the overall quality, 6 is the measuring aperture reference number (corresponding to a 0.15 mm diameter aperture) and 670 is the peak response wave length in nanometers. A 1.5 corresponds to a C grade in ANSI standard X3.182 – 1990.

2.1.3 Symbol Dimensions

X dimension: As large an X dimension as practical should be used, with a minimum nominal X dimension of 0.25 mm and a maximum nominal X dimension of 1 mm.

Finder pattern: The width of the finder pattern shall equal X.

Alignment pattern: The width of the alignment pattern shall equal 2X.

Quiet zone: The minimum quiet zone is equal to X on all four sides. For applications with moderate to excessive reflected noise in close proximity to the symbol, a quiet zone of 2X to 4X is recommended.

2.2 Scanners

Data Matrix symbols must be read using an imaging scanner. These scanners create an image of the symbol and then decode the message from the image. While all imaging scanners can also read linear bar codes, the reverse is not true. That is, not all scanners that can read linear bar codes can read 2-D bar codes. Therefore, facilities may have to invest in new scanners in order to read Data Matrix symbols.

2.3 Encoding Information

2.3.1 Single Data Structure

When a single data structure is to be encoded into a 2-D symbol, it is coded exactly as it is within a linear bar code: the data identifiers and the data content are encoded. For example, a Donation Identification Number (DIN) on a sample tube would be encoded as:

=A99991712345600

The symbol for this information would be: 

In addition, to a sample tube label, a Global Registration Identifier for Donors (GRID) or the Single European Code (SEC) might also be coded as a single data structure encoded within a 2-D symbol.

Because of the simplicity of encoding a single data structure, it will not be discussed further.

2.3.2 Multiple Data Structures

Data Matrix is ideal for encoding a great deal of information in a small space. Because Data Matrix allows up to 2335 alphanumeric characters or 3116 numeric characters to be encoded, information from multiple data structures can be encoded into a single symbol. This is accomplished through the use of the Compound Message [Data Structure 023]. Details for use of this data structure may be found in the *ISBT 128 Standard Technical Specification* (ST-001). Its structure is:

=+aabbb

Where:

=+ is the data identifier;

aa is the number of ISBT 128 data structures that follow;

bbb is either:

- all zeroes – indicating this is an undefined message, i.e., only the number of data structures is identified, but not what each one is or the order in which they occur.

- a three-digit number referencing an entry in an ICCBBA-maintained table that defines the sequence of the data structures within a compound message (see Table W2, [RT017] ICCBBA-Specified Compound Messages).

Note: Because of the complexity created by multiple product categories and the many codes that would result from permutations of order of data structures, ICCBBA now encourages the use of undefined messages.

Rules for constructing compound messages.

1. A compound message shall comprise a string of ISBT 128 data structures (excluding nationally-defined structures), beginning with the Compound Message [Data Structure 023].

2. Data structures shall be combined with no intervening characters. Each data structure shall begin with its data identifier characters.

3. The string shall only contain ISBT 128 data structures.

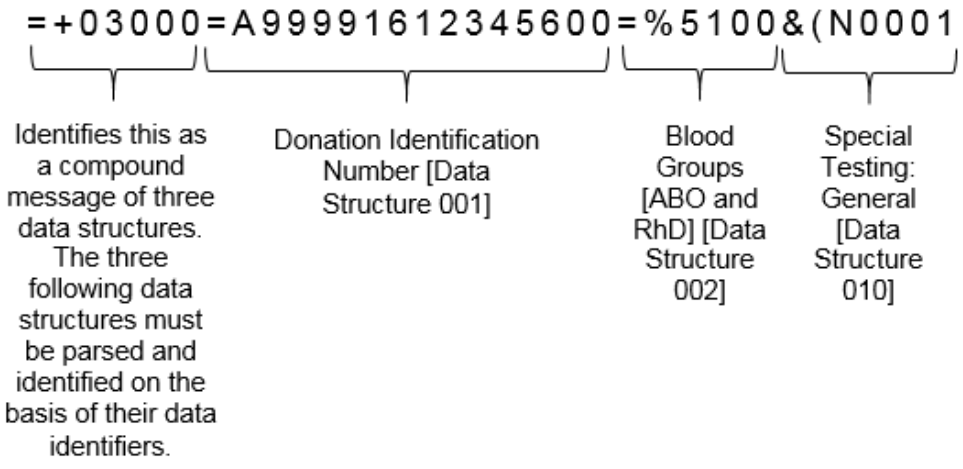
4. The number of data structures following the Compound Message Data Structure shall be indicated in element aa of the Compound Message Data Structure.

5. If the sequence of the message is unspecified, the Compound Message Data Structure shall have elements bbb set to zeroes and element aa shall be set as specified in Rule 4.

6. If a specified sequence is used, the reference number of the selected message from Table RT017 shall be included in element bbb of the Compound Message Data Structure. The order of the data structures shall be that shown on Table RT017 for the reference number selected.

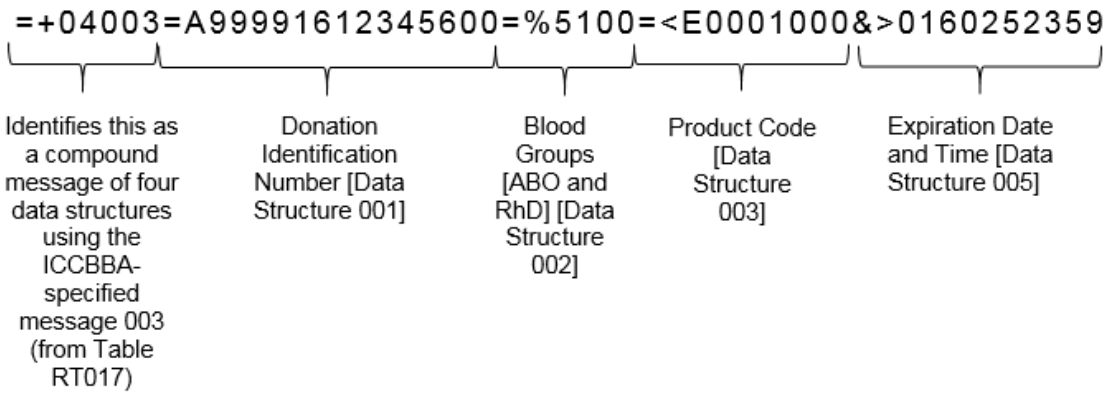
ICCBBA-specified compound messages are defined in Table W2, ICCBBA-Specified Compound Messages. While ICCBBA encourages the use of undefined messages, requests for additional entries may be submitted to the ICCBBA office (tech.manager@iccbba.org).

Example of a message not specified by ICCBBA is:



Example of an ICCBBA-specified message:

A compound message using an ICCBBA-specified message 003 from Table RT017 includes: Donation Identification Number [Data Structure 001], Blood Groups [ABO and RhD] [Data Structure 002], Product Code [Data Structure 003], and Expiration Date and Time [Data Structure 005]). It would be encoded:

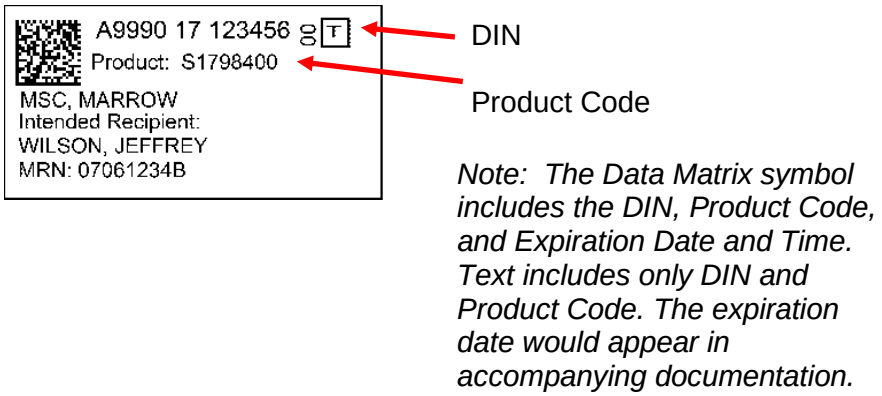


2.4 Affixed Labels

2.4.1 Required Text

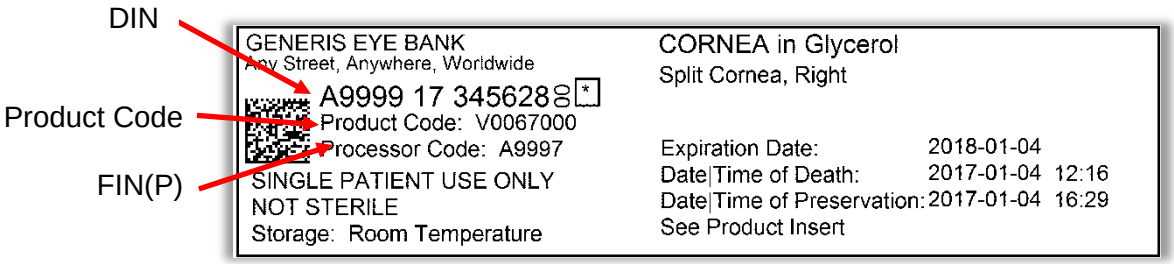
To support traceability, the DIN and Product Code (both the Product Description Code with the Division Codes) shall be present in text. If Product Divisions [Data Structure 032] and/or the Facility Identification Number of the processing facility [called the FIN(P)] [Data Structure 033 or 034] are used, they shall be included in the text.

Figure 2 2-D Symbol with Required Text (Cellular Therapy)



Note: The Data Matrix symbol includes the DIN, Product Code, and Expiration Date and Time. Text includes only DIN and Product Code. The expiration date would appear in accompanying documentation.

Figure 3 Required Text, Ocular Label



2.4.2 Bar Code Text

Bar code text is the interpretation of the data content within the 2-D symbol in terminology that is meaningful to the user. There may be insufficient space on the affixed label for all the associated bar code text to be displayed. In this case, some text may appear on attached or accompanying documentation provided that adequate controls are in place to ensure correct matching of this documentation to the labeled unit and that local regulations permit this.

2.4.3 Small Label Examples

Data Matrix symbols are ideal when the label is small or when a large amount of electronically-readable information must be carried on the label.

Figure 4 "Fold Over" Cellular Therapy Vertical Label

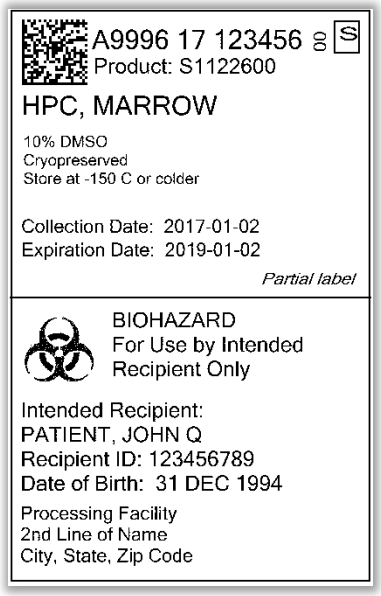


Figure 5 "Fold Over" Cellular Therapy Horizontal Label

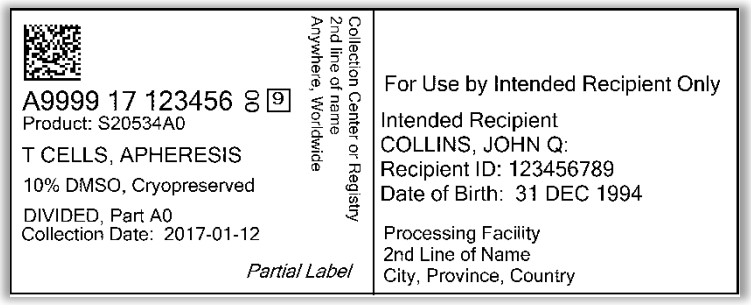


Figure 6 Tissue Product Label

2.4.4 100 mm x 100 mm Affixed Labels

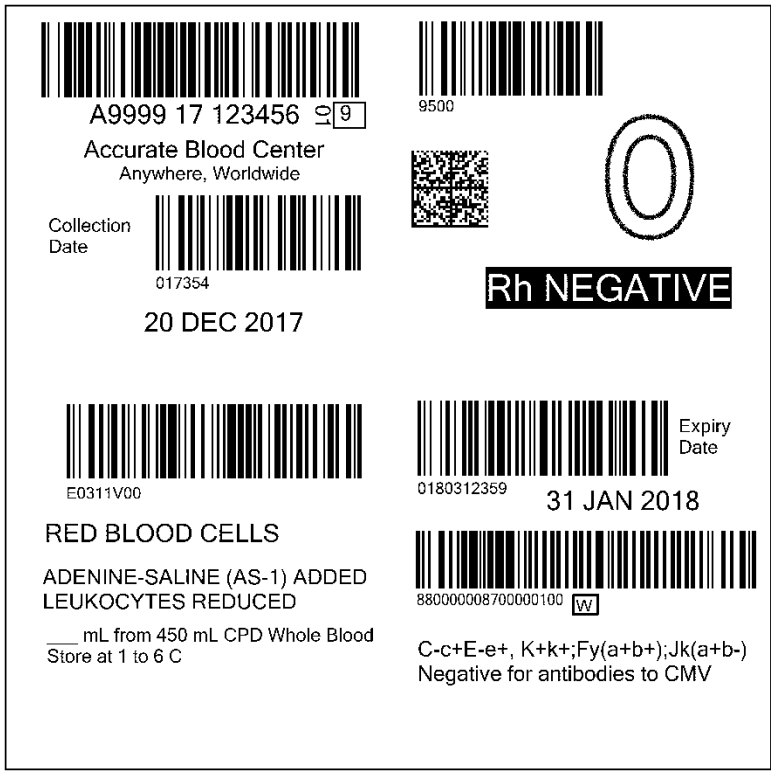
Users may find it more efficient to scan a single 2-D bar code rather than multiple linear bar codes.

Long term, a single 2-D symbol with no linear bar codes would be ideal . However, during a transition period that allows facilities time to upgrade software, both linear bar codes and a 2-D symbol may be present on a label. Appropriate control mechanisms shall be in place to ensure that all the information on the label (linear bar codes, 2-D bar codes, and text) is consistent.

Currently for blood products, linear bar codes shall be present on the label (see Figure 7). However, an advisory group to ICCBBA has created a proposal for a label with only a 2-D symbol.

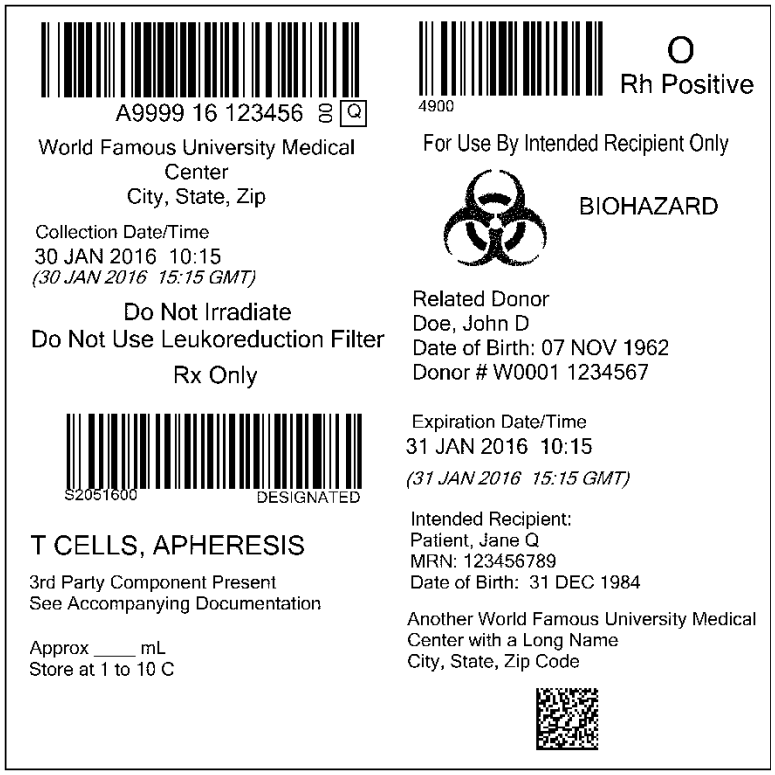
Labels for other MPHO may use either linear or 2-D symbols or both.

Figure 7 100 mm x 100 mm Blood Label



Note: When a 2-D symbol is the only symbol on a blood label, its exact placement on the label is currently being considered. A proposal has been made that, if approved, will locate the symbol on the upper half of the label. When the 2-D symbol is present with linear bar codes, it is considered a "transition label" allowing facilities time to develop the capacity to read and interpret 2-D symbols. In this case, the location of the 2-D symbol may be nationally-defined. In discussions of blood Technical Advisory Groups, the suggestion has been made to place the 2-D symbol as close to its eventual location as possible and thus this example shows the 2-D symbol in the upper half of the label. It is recommended that blood facilities check with ICCBBA before designing labels with 2-D symbols for the latest information.

Figure 8 100 mm x 100 mm Cellular Therapy Product Label



2.5 Attached or Accompanying Labeling

Some ISBT 128 data structures, such as the Infectious Markers [Data Structure 027], are not intended to be used on affixed product labels. Additionally, some product containers are too small to include all the information needed to ensure patient safety. Data Matrix symbols can be used to encode such information into a machine-readable format on the accompanying or attached documents. This can be done most simply by printing a label on a standard label printer and affixing it to the document(s). Alternatively, software can be created to print forms with the appropriate 2-D symbols.

Mechanisms must be in place to ensure such labeling is attached to the correct product. It is strongly recommended that the DIN be included in all messages.

3 Example Messages and Symbols

ICCBBA provides sample symbols for use in validation in *Technical Bulletin 10 Valid and Invalid Bar Codes for use in ISBT 128 Validations* (IG-013).

3.1 Example 1

The Data Structures desired in a compound message are:

- Donation Identification Number [Data Structure 001]
- Blood Groups [ABO and RhD] [Data Structure 002]
- Product Code [Data Structure 003]
- Expiration Date and Time [Data Structure 005]
- Special Testing: Red Blood Cell Antigens – General [Data Structure 012]

Per Table W2, Data Structure 023 ICCBBA-Specified Compound Messages [RT017] on the ICCBBA Website, this is a standard compound message: 010.

Table 1 Excerpt from RT017 – Example 1

ID	Number of Data Structures	Data Structure Numbers	Data Structures
010	05	[001];[002];[003];[005];[012]	Donation Identification Number;Blood Groups [ABO and RhD];Product Code;Expiration Date and Time;Special Testing: Red Blood Cell Antigens - General

The message desired is:

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991612345621	=A99991612345621
Blood Group	A, Rh Positive	=%6200
Product Code	RED BLOOD CELLS|CP2D>AS3/500mL/refg from a volunteer blood donor, undivided.	=<E0366V00
Expiration Date and Time	31 JAN 2017, 23:59	&>0170312359
Special Testing: Red Cell Antigen General	C+, c-, E-, e+	=\699999999999999999

A compound message with this data would be:

Data Characters	Meaning of Data Characters
=+	Data identifier
05	There are five data structures in the message
010	This is standard message 010 from Table RT017
=A99991612345621	Data identifier and data content for DIN
=%6200	A, Rh Positive
=<E0366V00	E0366V00
&>0170312359	31 JAN 2017, 23:59
=\699999999999999999	C+, c-, E-, e+

The data string would therefore be:

=+05010=A99991612345621=%6200=<E0366V00&>0170312359=\699999999999999999

The Data Matrix symbol would be: 

This symbol, created with an X dimension of approximately 0.3 mm, is 8 mm square.

3.2 Example 2

The Data Structures desired in the compound message are:

- Donation Identification Number [Data Structure 001]
- Blood Groups [ABO and RhD] [Data Structure 002]
- Product Code [Data Structure 003]
- Expiration Date and Time [Data Structure 005]
- Special Testing: General [Data Structure 010]

Per Table W2, Data Structure 023 ICCBBA-Specified Compound Messages [RT017] on the ICCBBA Website, this is a standard compound message: 009.

Table 2 **Excerpt from RT017 – Example 2**

ID	Number of Data Structures	Data Structure Numbers	Data Structures
009	05	[001];[002];[003];[005];[010]	Donation Identification Number;Blood Groups [ABO and RhD];Product Code;Expiration Date and Time;Special Testing: General

The message desired is:

Data Structure	Information to transfer	Data Identifier and Code
DIN	A9999 16 123356 00	=A99991612335600
Blood Groups [ABO and RhD]	A, Rh Negative	=%0600
Product Code	Apheresis PLATELETS|ACD-A/XX/20-24C|Irradiated|ResLeu:<1E6 from a volunteer blood donor, undivided.	=<E3929V00
Expiration Date and Time	12 JAN 2016, 23:59	&>0160122359
Special Testing: General	CMV Seronegative	&(N0008

A compound message with this data would be:

Data Characters	Meaning of Data Characters
=+	Data identifier
05	There are five data structures in the message
009	This is standard message 009 from Table RT017
=A99991612335600	Data identifier and data content for DIN
=%0600	A, Rh Negative
=<E3929V00	E3929V00
&>0160122359	12 JAN 2016, 23:59
&(N0008	CMV seronegative

The data string would therefore be:

=+05009=A99991612335600=%0600=<E3929V00&>0160122359&(N0008

The Data Matrix symbol would be: 

This symbol, created with an X dimension of approximately 0.3 mm, is 8 mm square.

3.3 Additional Examples of Data Matrix Symbols

Compound Message 001: Donation Identification Number [Data Structure 001];Product Code [Data Structure 003]

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991622335624	=A99991622335624
Product Code	Apheresis FRESH FROZEN PLASMA|ACD-A/XX/<=-25C from a volunteer blood donor, undivided.	=<E3893V00

Data String: =+02001=A99991622335624=<E3893V00

Symbol: 

Compound Message 002: Donation Identification Number [Data Structure 001];Blood Groups [ABO and RhD] [Data Structure 002]

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991631335600	=A99991631335600
Blood Groups [ABO and RhD]	B, Rh Negative	=%1700

Data String: =+02002=A99991631335600=%1700

Symbol: 

Compound Message 003: Donation Identification Number [Data Structure 001];Blood Groups [ABO and RhD] [Data Structure 002];Product Code [Data Structure 003];Expiration Date and Time [Data Structure 005]

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991672335600	=A99991672335600
Blood Groups [ABO and RhD]	AB, Rh Negative	=%2800
Product Code	RED BLOOD CELLS|CPD>AS5/450mL/refg Volunteer donor, undivided	=<E0385V00
Expiration Date and Time	03 JAN 2017, 23:59	&>0170032359

Data String: =+04003=A99991672335600=%2800=<E0385V00&>0170032359

Symbol: 

Compound Message 004: Donation Identification Number [Data Structure 001];Product Code [Data Structure 003];Expiration Date and Time [Data Structure 005]

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991672335700	=A99991672335700
Product Code	RED BLOOD CELLS|CPD>AS5/450mL/refg, Volunteer donor, undivided	=<E0385V00
Expiration Date and Time	08 JAN 2017, 23:59	&>0170082359

Data String: =+03004=A99991672335700=<E0385V00&>0170082359

Symbol: 

Message not specified by ICCBBA (000): Donation Identification Number [Data Structure 001];Production Date and Time [Data Structure 009]

Data Structure	Information to transfer	Data Identifier and Code
DIN	A99991772335900	=A99991772335900
Production date and time	03 JAN 2017, 15:15	&}0170031515

Data String: =+02000=A99991772335900&}0170031515

Symbol: 

Additional examples of 2-D labels which may be used for validation are found in Technical Bulletin 10: Valid and Invalid Bar Codes for Use in ISBT 128 Validations (IG-013). This document may be found on the ICCBBA Website.

4 Notes for Software Developers

Software should be written to ensure that the full data string matches the information that should be present according to the first 5 characters of the compound message data structure (i.e., the number of data structures that should be present and, if it is an ICCBBA-specified message, which data structures according to Table RT017). Additionally, when the source of the information is identified using Table RT018 [Data Structures 024 and 025], the software should confirm that there is consistency (i.e., both data structures identify the same source).

Once verification is complete, the data string can be parsed into its individual data structure elements and handled in the same way as the corresponding linear bar code entry. In this way software can operate independently of the input format and products labeled with linear and 2-D codes can be handled simultaneously.

Each data structure in the string should be verified individually in the same way that their linear counterparts are verified.

