ISBT 128 STANDARD

Technical Specification

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1 Introduction

1.1 Purpose

The purpose of this document is to provide standards and guidance for the coding and labeling of human blood, cellular therapy products, tissues, and organs, as well as those plasma derivatives (see Glossary for definition of plasma derivative) for which ABO is relevant.

1.2 Scope

This document is a comprehensive description of the rules surrounding the use of ISBT 128 as well as guidance in the interpretation of these rules. It contains many, but not all, of the reference tables. Tables for the ISBT 128 Product Description Codes, Facility Identification Numbers, and Special Testing, General codes are too large for inclusion in this document. These databases may be found in the Tech Library Section of the ICCBBA Website (www.iccbba.org). Reference tables for Manufacturer Identification Codes and Structured Compound Messages are also found on the Website in the Tech Library section. Reference tables for Special Testing: HLA-A and –B Alleles [Data Structure 015], Special Testing: HLA-DRB1 Alleles [Data Structure 016], and Red Cell Antigens with Test History [Data Structure 030] are maintained on Websites of other organizations. Links to these Websites are found in Section 3.2.

This document is supplemented with other guidance documents that provide greater detail on how ISBT 128 may be implemented.

1.3 Intended Audience

This document is intended for all users of ISBT 128, as well as those interested in implementing the Standard. This includes:

- staff of facilities utilizing, or planning to utilize, the ISBT 128 Standard (management, information technology, validation, quality management, laboratory, etc.)
- software developers
- vendors of labels for blood, cellular therapy, and tissue products
- vendors of containers for blood and cellular therapy products
- vendors of products that utilize ISBT 128
- regulators and auditors

1.4 Normative References

ICCBBA:

Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions
ISBT 128 Standard—Labeling of Human Tissues
ISBT 128 Standard—Product Code Structure and Labeling - Cellular Therapy Products

ISBT 128 Standard—Product Code Structure and Labeling - Blood Components

These documents are found in the Tech Library section on the ICCBBA Website.

Other Standards and Guidelines:

ANSI MH10.8.2-2002: Data Identifier and Application Identifier Standard (9 August 2002).

ANSI X3.182 – Bar Code Print Quality Guideline.

http://webstore.ansi.org/

ISO/IEC 7064:2003(E): Information technology—Security techniques—Check character systems

ISO 8601 (2004) Data elements and interchange formats — Information interchange — Representation of dates and times

ISO/IEC 15415:2004(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Two-dimensional symbols (and correction ISO/IEC 15415:2004/Cor 1:2008).

ISO/IEC 15416:2000(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols

ISO/IEC 15417: 2007(E): Information technology—Automatic Identification and data capture techniques—Code 128 bar code symbology specification

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix (and correction ISO/IEC 16022:2006/Cor 1:2008**)**

http://www.iso.org/iso/en/prods-services/ISOstore/store.html

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.

1.5 Other References

ICCBBA:

ICCBBA publications are maintained on the ICCBBA Website. It is the responsibility of registered and licensed establishments to ensure that they have the most recent version of all ICCBBA publications by regularly consulting the listing maintained on the ICCBBA Website. The following listing is current as of the date on the front cover of this document.

Implementation Guides

Use of Data Matrix Symbols with ISBT 128
Use of Dimensions Data Structure [029]
Use of Red Cell Antigens with Test History Data Structure [030]
Use of the Manufacturers Data File
Use of Product Code Data Structure [003], Tissues
Choosing an On-Demand Label Printer

Technical Bulletins

Bulletin 5: Bar Code Scanner Implementation of ISBT 128 Concatenation
Bulletin 7: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution
Bulletin 8: Specification for ISBT 128 Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification
Bulletin 9: Blood Bag Identification Using ISBT 128 and GS1
Bulletin 10*:* Valid and Invalid Bar Codes for use in ISBT 128 Validations

Technical Notes

Note 1: Case Conversion
Note 2: Length of the Product Code Bar Code and Concatenation
Note 4: Manufacturer's Catalog Number and Lot Number (NOT Containers)

Introductory Booklets

ISBT 128 for Blood Components, An Introduction
ISBT 128 for Tissues, An Introduction
ISBT 128 for Cellular Therapy, An Introduction
ISBT 128, An Introduction to Bar Coding

Non-ICCBBA:

Palmer, RC. The Bar Code Book. 5th ed. Victoria, BC Canada: Trafford Publishing 2007.

ISO/IEC 15459-2:2006(E): Information technology — Unique identifiers — Part 2: Registration procedures

ISO/IEC 15459-2:2006(E): Information technology — Unique identifiers — Part 3: Common rules for unique identifiers

1.6 Background

The ISBT 128 Standard has been utilized in various countries for many years. It has proven capable of achieving its purpose of conveying information about human transplantation and transfusion products accurately and unambiguously. As communication technology advances, it becomes increasingly important that ISBT 128 is not linked to a particular data transfer technology. This means a variety of delivery mechanisms can be used to transfer information.

From its original role as a labeling standard, ISBT 128 has been re-defined as: “An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.”

The ISBT 128 Standard is a dynamic standard. Changes occur continually over the years as different needs are recognized. Proposals for change follow a managed process, being carefully reviewed by experts in the field in many countries before they are incorporated into the Standard. Proposals are posted on the ICCBBA Website and users from ICCBBA registered facilities can view and comment upon proposals. Every effort is made to ensure that all changes are backward compatible.

1.7 New in This Version

The following table indicates the major changes between Version 4.0.1 and Version 4.1.0. Actual changes or additions to requirements of the ISBT 128 Standard are in bold print; changes to formatting or organization, or additional guidance, are in regular print.

When changes were a result of a formal proposal, the number of the proposal is listed in the Rationale column.

ISBT 128 Standard Technical Specification Version Control: Version 4.0.1 vs. Version 4.1.0

	Version 4.0.1 Chapter, Section, Table, or Figure	Version 4.1.0 Chapter, Section, Table, or Figure	Change	Rationale
1		1.5	Added references to ISO standards	Completeness
2	2.1, Table 1	2.1, Table 1	Changed the Name of ASCII Value 96 from dipthong to grave accent	Correction
3	2.3, Table 2 and 2.4.11	2.3**,** Table 2 and 2.4.11	Changed Data Structure 011 from "Withdrawn" to "Retired." (All references to this table were also changed to "Retired".)	Consistent with definition of "Retired" that has been added to the Glossary
4	**2.3, Table 2, 2.4.15, and 2.4.16**	**2.3, Table 2, 2.4.15, and 2.4.16**	**Indicated that Data Structures 015 and 016 are retired. (All references to this table were also changed to "Retired".)**	**These data structures reference a table maintained by the European Bioinformatics Institute as part of the international ImMunoGeneTics project (IMGT). In April 2010, the IMGT table was changed to require more characters to express HLA genotypes. Data Structures 015 and 016 cannot be expanded to accommodate the additional characters.** (Section 3.2.1 provides details on current recommendation if this table is being used.)

	Version 4.0.1 Chapter, Section, Table, or Figure	Version 4.1.0 Chapter, Section, Table, or Figure	Change	Rationale
5	2.4.3	2.4.3	Reformatted the text utilizing bullets to describe the purpose of Data Structure 003	Clarify that while encoding the type of donation is optional, encoding whether or not the product has been divided is not optional
6	2.4.3	2.4.3	Indicated the use of national or local product description codes for products produced at one, or only a very small number of facilities, is an example only.	Clarity. There are other times when national or local product description codes are appropriate.
7	2.4.3	2.4.3	Added the term “pack” to the description of the use of division codes for tissues.	For tissues, the last three characters of the product code may be used for divisions of identical products or the characters may be used to indicate multiple non-identical products (packs) from a single donation event.
8	2.4.6	2.4.6	Indicated the data structure encodes the date of collection or recovery.	For tissue, recovery is the appropriate term.
9	2.4.7	2.4.7	Indicated the data structure encodes the date of collection or recovery.	For tissue, recovery is the appropriate term.
10	2.4.10	2.4.10	Indicated that the data structure encodes whether the product has been phenotyped rather than indicate that it conveys a red cell phenotype.	Clarity
11	2.4.12	2.4.12	Indicated the data structure can convey information about Parvovirus B19.	Completeness.
12	3.1 Table 3	3.1, Table 3	Defined flags 12 as “Affixed partial label” and 13 as “Attached label”	Allow mechanism to match an attached label to an affixed label to ensure accurate association of information on the two labels

	Version 4.0.1 Chapter, Section, Table, or Figure	Version 4.1.0 Chapter, Section, Table, or Figure	Change	Rationale
13	**3.1, Table 14**	**3.1, Table 14**	**Added HLA-B82 and HLA-B83 to the table**	**Additional HLA alleles identified by IMGT.**
14	**3.1, Table 16**	**3.1, Table 16**	**Indicated Table 16 [RT015] is retired. (All references to this table were also changed to indicate "Retired".)**	**This table supports Data Structure 015 that has been retired.**
15	**3.1, Table 17**	**3.1, Table 17**	**Added a code for affixed labels**	**For cellular therapy applications, the patient date of birth and identification number are printed on the affixed label**
16	**3.1, Table 20**	**3.1, Table 20**	**Added codes for tare weight of container and tare weight of container plus tubing**	**At the request of a user.**
17	**3.2.1**	**3.2.1**	**Updated the reference to IMGT website to indicate the crosswalk table between current terminology and that in use prior to April 2010. Noted that Data Structures 015 and 016 do not support the current IMGT nomenclature.**	**Data Structures 015 and 016 cannot support the current IMGT nomenclature. This link provides a reference for nomenclature used prior to April 2010 that may be used in Data Structures 015 and 016.**
18	4.2	4.2, Table 29 [RT043]	Added version table for Special Testing General database	Completeness
19	**5.1.3**	**5.1.3**	**Indicated that the minimum height requirement for Code 128 linear bar codes applies only to labels on products that will leave the facility in which the bar code was created.**	**Labels that leave a facility need to be scannable by all common scanners. Therefore a minimum size is required. For bar codes that are only used internally, validation studies can be done to determine the minimum height required.**

	Version 4.0.1 Chapter, Section, Table, or Figure	Version 4.1.0 Chapter, Section, Table, or Figure	Change	Rationale
20	6.4.2	6.4.2	Indicated that the bar code height could be reduced to 15% of bar code length, with an example that if the bar code length is 43 mm, the height could be approximately 7 mm	Previously indicated 8 was the minimum height. Provides a little more flexibility.
21	6.5.1	6.5.1	Separated requirements for which data structures must be included in a Data Matrix symbol for blood and cellular therapy products.	ABO/Rh may not be known at the time a cellular therapy product is frozen. Not all cellular therapy products have expiration dates.
22	6.5.2	6.5.2	Indicated that even on a small label, an eye-readable text product code must be present	Clarification. Traceability requires both the Donation Identification Number and a Product Code (both Product Description Code and Division/Pack Code). Even if there is inadequate space for a machine readable Product Code (or a 2-D label is used), the Product Code must appear in text on the label.
23	6.6.2	6.6.2	Changed example to a Red Cell phenotype	Previous example (HLA genomic typing) used a retired data structure.
24	12	12	Changed chapter title from “Role of ICCBBA” to “ICCBBA”	To reflect broader content of the chapter.
25		**12.4**	**Added ICCBBA’s Issuing Agency Identifier Code under ISO/IEC 15459-2:2006(E)**	**ICCBBA has recently been given an Issuing Agency Identifier Code.**
26	Acronyms	Acronyms	Added IMGT to Acronym list	Completeness

	Version 4.0.1 Chapter, Section, Table, or Figure	Version 4.1.0 Chapter, Section, Table, or Figure	Change	Rationale
27	Glossary	Glossary	Explained that the second data identifier cannot be dropped from the DIN even in situations where the data structure is unambiguously and explicitly defined.	Clarification
28	Glossary	Glossary	Revised definition of label to indicate it "may" carry one or more bar codes	With the addition of a definition for an attached label, there are times when a label may not have a bar code
29	Glossary	Glossary	Added definition for partial label	Clarification
30	Glossary	Glossary	Added a definition for Plasma Derivative.	Term is used in the Introduction to this document and may not have the same definition internationally.
31	**Glossary**	**Glossary**	**Added a definition for "retired."**	**This term has been given a special meaning within the ISBT 128 standard to indicate a data structure or code that is retained for backward compatibility, but should be phased out.**
32	Glossary	Glossary	Grouped definitions for label and donation type	Easier for users to compare definitions
33	Glossary	Glossary	Added "recovery" to definition of "facility"	To include for tissue recovery organizations
34	Glossary	Glossary	Updated graphic for text terminology	Use a 2012 example
35	Appendix A	Appendix A	Updated example of calculation	Use a 2012 example
36	Appendix C	Appendix C	Updated example labels	Use 2011 or 2012 dates
37	**Appendix D**	**Appendix D**	**Indicated Table RT015 is retired**	**This table supports Data Structure 015 that has been retired.**
38	Appendix D	Appendix D	Changed the word "Withdrawn" to "Retired" for tables 8 and 11.	Consistent with definition of "Retired" that has been added to the Glossary

2 Data Structures

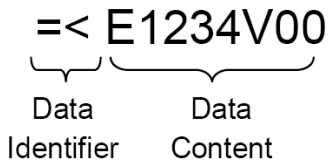
Data structures defined in this document are internationally agreed entities for encoding information relevant to transfusion medicine and transplantation. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure 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.

Data structures generally comprise two elements:

- Data identifiers: a two-character code that identifies the data structure (described in more detail in 2.1)
- Data content: the data characters that provide the information to be conveyed (e.g., coded information that conveys the unit is A, RhD positive)

Figure 1 Data Structure



Some information may be conveyed at different levels of detail in different data structures. For example, the volume of a blood product may be conveyed in two data structures:

- Product Code [Data Structure 003] as part of the Final Volume attribute group (e.g., equal to or greater than 200 mL to less than 400 mL) or
- Dimensions [Data Structure 029] as a specific value (e.g., 223 mL).

If a facility chooses to use more than one data structures to convey similar information, systems shall be in place to ensure accurate entry of data so that the information being conveyed is consistent.

2.1 Data Identifiers

Data identifier characters shall be used in circumstances in which the context of the data structure presentation makes it necessary to also indicate the nature of the information being conveyed. For example, in bar codes the data identifiers are essential to ensure correct interpretation.

However, in applications in which the data structures are being used within an existing framework, such as an electronic data interchange (EDI) message, the data identifiers

may be omitted provided that the message definition unambiguously indicates that the field contains a specific ISBT 128 data structure.

Each ISBT 128 data structure shall have two ASCII characters that serve to identify the data structure. The first ASCII character is the first character of the data identifier. It shall always be = (ASCII 61) or & (ASCII 38). These identifiers have been reserved by ANSI (ANSI MH10.8.2-2002) as ISBT 128 data identifiers to distinguish ISBT 128 data structures from all others.

In ICCBBA internationally defined data structures, the second character of the data identifier shall be a non-alphanumeric ASCII character. The exception to this is the Donation Identification Number (DIN) [Data Structure 001]. The DIN shall have a first data identifier character of = and a second data identifier character that can be any of the alphanumeric characters 1–9, A–N, P–Z (but not a–z). Note that for this data structure only, the second data identifier character shall be the first character of the data content.

Data identifiers with the first character of "&", and a second character from the range a-z shall be reserved for non-ICCBBA defined data structures (see section 2.5). The data identifier pairs &; and &! shall be hybrid structures which have an ICCBBA defined context but non-ICCBBA defined structure.

The characters used in ISBT 128 data identifiers are shown in Table 1, page 19, together with their ASCII values. All ICCBBA documents shall use the US ASCII mapping shown in Table 1. The character assigned to a particular ASCII value may vary according to the character map being used, but the ASCII value itself provides the definitive description of the data identifier character.

Data identifiers for ISBT 128 data structures shall be as indicated in Table 2, beginning on page 21.

Table 1 Code 128 Subset B Characters Available for Use as ISBT 128 Data Identifiers [RT001]

ASCII Value	Character	Name
33	!	exclamation mark
34	"	inch, double quotation mark
35	#	number sign
36	$	dollar sign
37	%	per cent sign
38	&	ampersand
39	‘	foot, single quotation mark
40	(	left parenthesis
41	)	right parenthesis
42	*	asterisk
43	+	plus sign
44	,	comma
45	-	dash
46	.	period
47	/	forward slash
58	:	colon
59	;	semicolon
60	<	less than
61	=	equal to
62	>	greater than
63	?	question mark
64	@	at sign
91	[	left square bracket
92	\	backward slash
93	]	right square bracket
94	^	circumflex, caret
95	_	underscore
96	`	grave accent
123	{	left brace
124	|	vertical bar
125	}	right brace
126	~	tilde

2.2 The Role of Data Identifiers in ISBT 128 Bar Codes

As indicated in Figure 1, ISBT 128 bar codes comprise two elements: data identifier characters and data content.

In order to accurately interpret information from an ISBT 128 bar code, application software shall carry out the following two steps before interpreting the data values:

1. Analyze the data identifier characters to ensure that the bar code entered is of the correct type;
2. Verify that the length and format of the data characters match that defined for the corresponding data structure.

Failure to carry out these checks could lead to incorrect assignment of critical information.

The following example illustrates this.

An ISBT 128 ABO/RhD Blood Groups [Data Structure 002] bar code for an A, RhD Positive unit will read as:

=%6200

where "=%" are the data identifier characters indicating that this is an ABO/RhD Blood Groups data structure, and "6200" are the data values for A, RhD Positive.

A Special Testing: Red Blood Cell Antigens — General [Data Structure 012] bar code on a Group O, RhD negative unit could have the value:

=\620000000000000000

If the data identifier characters are ignored by the application software, entry of this second bar code in response to a blood groups prompt could cause the system to incorrectly assign the unit as A, RhD Positive.

2.3 Data Structure Index

An index of data structures is provided in Table 2, beginning on page 21, which cross references them to their descriptions in this document.

Table 2 Index of Data Structures [RT003]

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content	See Section
			ASCII Value		ASCII Value		
001	Donation Identification Number	=	61	A–N; P–Z; 1–9		αppppyynnnnnnff	2.4.1
002	Blood Groups [ABO and Rh D]	=	61	%	37	ggre	2.4.2
003	Product Code	=	61	<	60	αooootds	2.4.3
004	Expiration Date	=	61	>	62	cyyjjj	2.4.4
005	Expiration Date and Time	&	38	>	62	cyyjjjhhmm	2.4.5
006	Collection Date	=	61	*	42	cyyjjj	2.4.6
007	Collection Date and Time	&	38	*	42	cyyjjjhhmm	2.4.7
008	Production Date	=	61	}	125	cyyjjj	2.4.8
009	Production Date and Time	&	38	}	125	cyyjjjhhmm	2.4.9
010	Special Testing: General	&	38	(	40	zzzzz	2.4.10
011	Special Testing: Red Blood Cell Antigens **[RETIRED]**	=	61	{	123	aaaaaaaaaaaaaaaaii	2.4.11
012	Special Testing: Red Blood Cell Antigens -- General	=	61	\	92	aaaaaaaaaaaaaaaaii	2.4.12
013	Special Testing: Red Blood Cell Antigens -- Finnish	&	38	\	92	aaaaaaaaaaaaaaaaii	2.4.13
014	Special Testing: Platelet HLA	&	38	{	123	AAAABBBBCCCCCCC	2.4.14

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content	See Section
			ASCII Value		ASCII Value		
	and Platelet Specific Antigens [Data Structure 014]					CDD	
015	Special Testing: HLA-A and -B Alleles **[RETIRED]**	=	61	[	91	EEEEFFFFGGGGHHHHLM	2.4.15
016	Special Testing: HLA-DRB1 Alleles **[RETIRED]**	=	61	"	34	IIIIJJJJMMMMMMMMM	2.4.16
017	Container Manufacturer and Catalog Number	=	61	)	41	bqqwwwwwww	2.4.17
018	Container Lot Number	&	38	)	41	xxxxxxxxxx	2.4.18
019	Donor Identification Number	=	61	;	59	αppppvvvvvvvvvvvvvv	2.4.19
020	Staff Member Identification Number	=	61	'	39	αppppuuuuuu	2.4.20
021	Manufacturer and Catalog Number: Items Other Than Containers	=	61	-	45	NNOOOOOOOO	2.4.21
022	Lot Number: Items Other Than Containers	&	38	-	45	PPPPPPPPPP	2.4.22
023	Compound Message	=	61	+	43	aabbb	2.4.23
024	Patient Date of Birth	=	61	#	35	aayyyymmdd	2.4.24
025	Patient Identification Number	&	38	#	35	aallxx…xx	2.4.25
026	Expiration Month and Year	=	61	]	93	yyyymm	2.4.26

Ref	Data Structure Name	First Character of the Data Identifier		Second Character of the Data Identifier		Data Content	See Section
			ASCII Value		ASCII Value		
027	Infectious Markers	&	38	“	34	nnnnnnnnnnnnnnnnn	2.4.27
028	Product Consignment	=	61	$	36	αppppyynnnnnccdd	2.4.28
029	Dimensions	&	38	$	36	nnaabbbbccccccdee	2.4.29
030	Red Cell Antigens with Test History	&	38	%	37	nnnpppppprrss	2.4.30
	Data structures not defined by ICCBBA	&	38	a-z		These data identifiers may be assigned by a facility or a regional, national, or supranational authority,	2.5.1
	Reserved Data Identifiers for a Nationally-Specified Donor Identification Number	&	38	;	59	Defined nationally	2.5.2
	Confidential Unit Exclusion Status Data Structure	&	38	!	33	Defined nationally	2.5.3

2.4 Description of the Data Structures

2.4.1 Donation Identification Number [Data Structure 001]

Note: This is the only data structure in which the second character of the data identifier shall be part of the data content.

Purpose: Data Structure 001 shall specify a Donation Identification Number that is a unique identification of a donation event [collection or recovery] or a product pool from anywhere in the world over a one hundred year period.

Structure: =αppppyynnnnnnff

Element	Length	Type
=	1	data identifier, first character
α	1	data identifier, second character alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A-N, P-Z, 0-9}; second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future (e.g., if α = A and pppp = BC12, the αpppp will be ABC12)
yy	2	numeric {0–9}
nnnnnn	6	numeric {0–9}
ff	2	numeric {0–9}

The fifteen (15)-character data content string, **αppppyynnnnnnff**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) and shall be encoded and interpreted by reference to the ICCBBA Registered Facilities database published and maintained by ICCBBA in the password-protected area of the ICCBBA Website

yy shall specify the last two digits of the year in which the donation was collected or recovered (or, in the case of a tissue processing facility assigning a DIN, this may be the year in which the first product from the donation event was processed)

Notes: In practice, this is the "nominal" year. To cut down on wastage, Donation Identification Number labels may be used for up to one month in the year before, and one month in the year after, the year shown on the label.

In the case of a tissue processing facility assigning a DIN, the DIN year code may be the year of the donation event OR the year in which the first product was processed. Usage shall be consistent within a facility. That is, if the DIN year code is the year the first tissue from the donation event was processed, the facility must always use the year the first tissue from a donation event was processed to determine the year code.

nnnnnn shall specify a serial number indicating the particular collection or recovery within the given year for the facility identified by the FIN

ff are "flag characters." Use of non-data flag characters "ff" shall conform to national guidelines, if such guidelines exist. As shown in Table 3 on page 67, there are three general types of usage:

- Type 1: Two-digit characters used for process control and defined by ICCBBA
- Type 2: Two-digit characters used for process control, but locally defined
- Type 3: A weighted ISO/IEC 7064 modulo 37-2 check character on the entire thirteen character DIN (see Appendix A for method of calculation). Because this check character acts on the entire data portion of the Donation Identification Number, encoding the check character in the bar code data acts as a secondary check within the bar code itself, further improving the already excellent scanning error resistance of the ISBT 128 symbology. More importantly, it provides a data transmission check character to ensure accurate communication of the scanned bar code to the host computer.

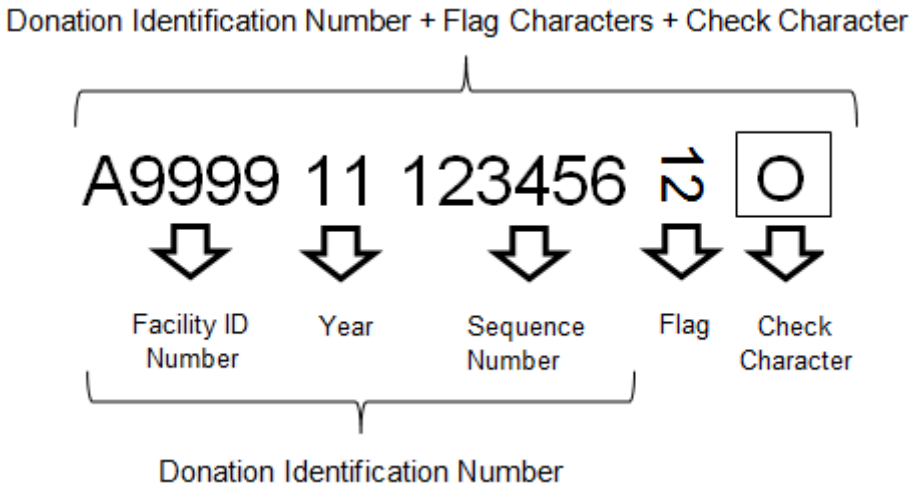
When not used, the value of the flags shall be 00.

Type 2 flag characters shall only be interpreted by the facility that has defined them or within the group of facilities that have agreed on a common definition.

For a description of one way in which flags can be used see *Technical Bulletin Number 7, Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution* available on the ICCBBA Website.

As shown in Figure 2 the combination, αppppyynnnnnn, forms the Donation Identification Number (DIN). Flag characters, while a part of the Donation Identification Number Data Structure, are not a part of the Donation Identification Number itself. Likewise, the keyboard entry check character (see Appendix A) is not a part of the Donation Identification Number. Both the flag characters and the keyboard entry check character are for process control and are not part of the unique identification of the product.

Figure 2 Donation Numbering



2.4.2 Blood Groups [ABO and RhD] [Data Structure 002]

Purpose: Data Structure 002 EITHER

- Shall indicate the blood groups [ABO and RhD] of a product and
- May convey information regarding C, c, E, e, K, or Miltenberger phenotypes and/or
- May include information defining the type of donation or collection

OR

- Shall convey special messages such as the status of a donation or collection, the blood group of pooled products, or processing instructions.

Structure: =%ggre

Element	Length	Type
=	1	data identifier, first character
%	1	data identifier, second character
gg	2	alphanumeric {A–Z; a-z, 0–9}
r	1	alphanumeric {A–Z; 0–9}
e	1	alphanumeric {A–Z; 0–9}

The four (4)-character data content string, **ggre**, shall be encoded and interpreted as follows:

gg shall

EITHER

specify ABO and RhD blood groups and type of donation or collection information and shall be encoded and interpreted by reference to Table 4, page 68

OR

specify a range of special messages as shown in Table 5, page 70

r shall specify RhD and Kell or Miltenberger phenotypes and shall be encoded and interpreted by reference to Table 6, page 71. A value of 0

(zero) shall be used if the data structure does not contain information about these phenotypes

e shall be reserved for future use. The value of e shall always be set to 0 (zero)

2.4.3 Product Code [Data Structure 003]

Purpose: Data Structure 003 shall:

- identify a product intended for human use according to the ISBT 128 scheme of Class, Modifier, and Attribute(s)
- optionally encode information about the type of donation or collection, and
- encode whether or not the product has been divided

Structure: =<αooootds

Element	Length	Type
=	1	data identifier, first character
<	1	data identifier, second character
α	1	alphabetic {A–Z} See below
oooo	4	numeric {0–9}
t	1	alphanumeric {A–Z; a–z; 0–9} (depends on value of α, see below)
d	1	alphanumeric {A–Z; 0–9}, (depends on value of α, see below)
s	1	alphanumeric {a–z; 0–9} (depends on value of α, see below)

The eight (8)-character data content string, **αooootds** shall be encoded and interpreted as follows.

αoooo shall specify the Product Description Code and shall be encoded and interpreted by reference to the Product Description Code database table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website (see 4.1).

α shall specify the following product groups:

- E or F - blood components
- S - cellular therapy products
- T - tissues
- X - derivatives
- A-D - national or local codes (see below).

oooo shall be interpreted through reference to the Product Description Code database

A-D National or Local Codes

The block of product description codes A0000-D9999 shall be reserved for use as nationally or facility defined product description codes. There shall be no international interpretation associated with these values.

These codes should ONLY be used where there is not an appropriate international code and there is good reason why an international code should not be allocated. For example, local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/regional/national, the user should contact the ICCBBA office.

National agencies may reserve a range of these values for national assignment. Where this is done it shall be the responsibility of the national agency to ensure that definitions are provided for use within the country and that products bearing such codes are not transferred outside the national boundary.

Individual facilities may also assign codes for their own use provided that these do not conflict with codes assigned at the national level. Where such codes are used, the facility shall ensure that definitions are provided for use within their service region, and that products bearing such codes are not transferred outside their normal distribution network. Care shall be taken in interpreting the product description from a local code as this will be specific to the supplier.

In all cases, the product definition for nationally or facility assigned codes shall be retained permanently for traceability purposes. Once assigned, codes shall not be reassigned.

The encoding and interpretation of **tds** shall depend upon the value of **α**.

If **α** is E, F, or S then:

t shall specify the type of donation and shall be encoded and interpreted by reference to Table 7, page 72

ds shall specify information as to whether the unit has been divided (see 8.1, page 118). If the unit has not been divided, **ds** shall be set to the default value of 00 (zero, zero)

d shall encode the first division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters

s shall encode the second division. Second level subdivisions (up to 26) shall be encoded using lower-case letters

Note: Divisions need not be equal and this nomenclature does not require this. See 8.1, page 118 for examples of use.

If **α** is T, **tds** shall specify a 3-digit number of divisions (or packs) of the product. If the product has not been divided (or there are not multiple product packs with the same product description code and DIN), **tds** shall be set to 000 (zero, zero, zero). For example of use, see 8.2, page 119.

If **α** is X, tds shall be reserved for future use and the value 000 shall be used.

If **α** is A-D, tds is not defined. If tds is set to something other than 000, it shall be defined in conjunction with the national/local code assignment.

Figure 3 Product Coding for Cellular Therapy or Blood

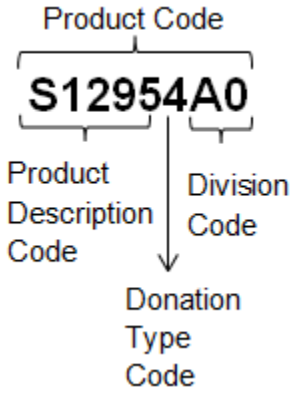
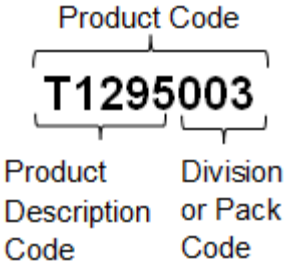


Figure 4 Product Coding for Tissues



2.4.4 Expiration Date [Data Structure 004]

Purpose: Data Structure 004 shall indicate the date at the end of which the item expires. This is intended to be used for supplies such as filters or solutions. While in the past this data structure has been used for blood, tissue, or cellular therapy products, it is now recommended that Data Structure 005 be used for these products.

Structure: =>cyyjjj

Element	Length	Type
=	1	data identifier, first character
>	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}

The six (6)-character data content string, **cyyjjj**, is encoded and interpreted as follows:

c shall specify the century of the year in which the item expires

yy shall specify the year within the century in which the item expires

jjj shall specify the ordinal (Julian) date on which the item expires

2.4.5 Expiration Date and Time [Data Structure 005]

Purpose: Data Structure 005 shall indicate the date and time when the product expires.

Structure: &>cyyjjjhhmm

Element	Length	Type
&	1	data identifier, first character
>	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}
hh	2	numeric { 0–9}
mm	2	numeric { 0–9}

The ten (10)-character data content string, **cyyjjjhhmm**, shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product expires

yy shall specify the year within the century in which the product expires

jjj shall specify the ordinal (Julian) date on which the product expires

hh shall specify the hour at which the product expires (00 to 23)

mm shall specify the minute at which the product expires (00 to 59)

A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of 2359 shall be encoded in the data structure.

2.4.6 Collection Date [Data Structure 006]

Purpose: Data Structure 006 shall indicate the date on which the product was collected or recovered.

Structure: =*cyyjjj

Element	Length	Type
=	1	data identifier, first character
*	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}

The six (6)-character data content string, **cyyjjj** shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product was collected or recovered

yy shall specify the year within the century in which the product was collected or recovered

jjj shall specify the ordinal (Julian) date on which the product was collected or recovered

2.4.7 Collection Date and Time [Data Structure 007]

Purpose: Data Structure 007 shall indicate the date and time of collection or recovery of the product.

Structure: &*cyyjjjhhmm

Element	Length	Type
&	1	data identifier, first character
*	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}
hh	2	numeric { 0–9}
mm	2	numeric { 0–9}

The ten (10)-character data content string, **cyyjjjhhmm**, shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product was collected or recovered

yy shall specify the year within the century in which the product was collected or recovered

jjj shall specify the ordinal (Julian) date on which the product was collected or recovered

hh shall specify the hour at which the product was collected or recovered (00 to 23)

mm shall specify the minute at which the product was collected or recovered (00 to 59)

A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of 2359 shall be encoded in the data structure.

2.4.8 Production Date [Data Structure 008]

Purpose: Data Structure 008 shall indicate the date on which the product was produced. While in the past this has been used for blood, tissue, or cellular therapy products, it is now recommended that Data Structure 009 be used for these products.

Structure: =}cyyjjj

Element	Length	Type
=	1	data identifier, first character
}	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}

The six (6)-character data content string, **cyyjjj** shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product was produced

yy shall specify the year within the century in which the product was produced

jjj shall specify the ordinal (Julian) date on which the product was produced

2.4.9 Production Date and Time [Data Structure 009]

Purpose: Data Structure 009 shall indicate the date and time of production of the product.

Structure: &}cyyjjjhhmm

Element	Length	Type
&	1	data identifier, first character
}	1	data identifier, second character
c	1	numeric {0–9}
yy	2	numeric {0–9}
jjj	3	numeric { 0–9}
hh	2	numeric { 0–9}
mm	2	numeric { 0–9}

The ten (10)-character data content string, **cyyjjjhhmm**, shall be encoded and interpreted as follows:

c shall specify the century of the year in which the product was produced

yy shall specify the year within the century in which the product was produced

jjj shall specify the ordinal (Julian) date on which the product was produced

hh shall specify the hour at which the product was produced (00 to 23)

mm shall specify the minute at which the product was produced (00 to 59)

A day shall be defined as beginning at midnight (00:00) and ending at 23:59. When a time is not specified, the default of 2359 shall be encoded in the data structure.

2.4.10 Special Testing: General [Data Structure 010]

Purpose: Data Structure 010 shall indicate special characteristics of a product such as whether it has been phenotyped, the presence of antibodies, CMV antibody status, Hemoglobin S status, etc.

Structure: &(zzzzz

Element	Length	Type
&	1	data identifier, first character
(	1	data identifier, second character
zzzzz	5	alphanumeric {A–Z; 0–9}

The five (5)-character data content string, **zzzzz** shall be encoded and interpreted by reference to the Special Testing database table (see 4.2, page 96) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

2.4.11 Special Testing: Red Blood Cell Antigens [Data Structure 011]

Data Structure 011 should not be used. It was **RETIRED** in Version 2.1.0 of the ISBT 128 Standard Technical Specification (August 2004) and replaced by Data Structures 012 and 013.

Purpose: Data Structure 011 is maintained for backwards compatibility. It provided information regarding red blood cell phenotypes and CMV antibody status of the product.

Structure: ={aaaaaaaaaaaaaaaaii

Element	Length	Type
=	1	data identifier, first character
{	1	data identifier, second character
aaaaaaaaaaaaaaaa	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaii**, shall be encoded and interpreted using Table 8, starting on page 73 and Table 11, page 79.

2.4.12 Special Testing: Red Blood Cell Antigens – General [Data Structure 012]

Purpose: Data Structure 012 shall provide information regarding red blood cell phenotypes, CMV antibody, IgA, Parvovirus B19, and Hemoglobin S status of the product.

Structure: =\aaaaaaaaaaaaaaaaii

Element	Length	Type
=	1	data identifier, first character
\	1	data identifier, second character
aaaaaaaaaaaaaaaa	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaii**, shall be encoded and interpreted using Table 9, starting on page 75 and Table 12, Page 80.

Common Rh antigens may be encoded together as a phenotype (Rh column 1 on Table 9, page 75) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column 1 shall be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens shall all be set to 9, ni (no information).

See Examples of Use in 8.3, page 120.

If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 9 and Table 12, positions 17 and 18 may be set to 00 (see Table 12) and information concerning the status of those antigens may be indicated on the label text. Alternatively, red cell antigens not found on these tables may be encoded using the Red Cell Antigens with Test History (Data Structure 030). For information on this data structure, see 2.4.30 on page 63.

2.4.13 Special Testing: Red Blood Cell Antigens — Finnish [Data Structure 013]

Purpose: Data Structure 013 shall provide information regarding red blood cell phenotypes, CMV antibody, and IgA status of the product. The Finnish table reflects different antigen distributions in the Finnish population.

Structure: &\aaaaaaaaaaaaaaaaii

Element	Length	Type
&	1	data identifier, first character
\	1	data identifier, second character
aaaaaaaaaaaaaaaa	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaii**, shall be encoded and interpreted using Table 10, starting on page 77 and Table 13, page 81.

If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 10 and Table 13, positions 17 and 18 may be set to 00 (see Table 13) and information concerning the status of those antigens may be indicated on the label text. Alternatively, red cell antigens not found on these tables may be encoded using the Red Cell Antigens with Test History (Data Structure 030). For information on this data structure, see 2.4.30 on page 63.

2.4.14 Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]

Purpose: Data Structure 014 shall provide information regarding HLA and HPA phenotypes, CMV antibody, and IgA status for platelet products. If genomic typing is used, only the first two digits of the type shall be encoded.

Structure: &{AAAABBBBCCCCCCCCDD

Element	Length	Type
&	1	data identifier, first character
{	1	data identifier, second character
AAAA	4	numeric {0–9}
BBBB	4	numeric {0–9}
CCCCCCCC	8	numeric {0–9}
DD	2	numeric {0–9}

Two **AA** values shall be encoded, followed by two **BB** values. To conform to practice the lower value shall always be listed first.

AAAA shall specify HLA-A antigens

BBBB shall specify HLA-B antigens

CCCCCCCC shall specify platelet-specific antigens, and IgA antigen and CMV antibody status

DD shall be reserved for future use. A default value of 00 (zero, zero) shall be used at this time

The eighteen (18)-character data content string, AAAABBBBCCCCCCCCDD, shall be encoded and interpreted using Table 14, beginning on page 82 and Table 15, page 84.

See Examples of Use in 8.4, page 121.

2.4.15 Special Testing: HLA-A and -B Alleles [Data Structure 015]

Data Structure 015 has been **RETIRED** as of this version of the ISBT 128 Standard Technical Specification (December 2011).

Purpose: Data Structure 015 is retained for backward compatibility. It provided information regarding HLA-A and - B alleles for Cellular Therapy and Tissue products. This is the first of a pair of data structures (see 2.4.16).

Structure: =[EEEEFFFFGGGGHHHHLM

Element	Length	Type
=	1	data identifier, first character
[	1	data identifier, second character
EEEE	4	numeric {0–9}
FFFF	4	numeric {0–9}
GGGG	4	numeric {0–9}
HHHH	4	numeric {0–9}
L	1	numeric {0–9}
M	1	numeric {0–9}

EEEE shall specify the first four digits of the first of the pair of HLA-A (usually) genomically-determined alleles

FFFF shall specify the first four digits of the second of the pair of HLA-A (usually) genomically-determined alleles

GGGG shall specify the first four digits of the first of the pair of HLA-B (usually) genomically-determined alleles

HHHH shall specify the first four digits of the second of the pair of HLA-B (usually) genomically-determined alleles

The 16-character data content string, **EEEEFFFFGGGGHHHH**, shall be encoded and interpreted using the table described in 3.2.1, page 91.

To conform to practice the lower value of each pair shall always be listed first.

Only the first four digits of the HLA-A and -B alleles are significant for transfusion and transplantation, because the fifth and any subsequent characters describe synonymous mutations.

00 shall be used after the first two characters to signify that typing of the respective HLA-locus has been performed using a method that does not allow allele discrimination at higher resolution than two (2) digits.

The value in the data structure for a null allele shall be 0000.

L shall specify the CMV antibody status (see Table 16, page 85)

M shall be reserved for future use; a default of 9 shall be used at this time.

For information on printing bar code text, see 6.6.3.6, page 116.

For examples of use, see 8.5, page 122.

2.4.16 Special Testing: HLA-DRB1 Alleles [Data Structure 016]

Data Structure 016 has been **RETIRED** as of this version of the ISBT 128 Standard Technical Specification (December 2011).

Purpose: Data Structure 016 is retained for backward compatibility. It provided information regarding HLA-DRB1 alleles for Cellular Therapy and Tissue products. This is the second of a pair of data structures (see 2.4.15).

Structure: ="IIIIJJJJMMMMMMMMMM

Element	Length	Type
=	1	data identifier, first character
"	1	data identifier, second character
IIII	4	numeric {0-9}
JJJJ	4	numeric {0–9}
MMMMMMMMMM	10	numeric {0–9}

IIII shall specify the first four digits of the first of the pair of HLA-DRB1 (usually) genomically-determined alleles

JJJJ shall specify the first four digits of the second of the pair of HLA-DRB1 (usually) genomically-determined alleles

The 8-character data content string, **IIIIJJJJ**, shall be encoded and interpreted using the table described in 3.2.1, page 91.

To conform to practice the lower value of each pair shall always be listed first. Only the first four digits of the HLA-DRB1 alleles are significant for transfusion and transplantation, because the fifth and any subsequent characters describe synonymous mutations.

00 shall be used after the first two characters to signify that typing of the respective HLA-locus has been performed using a method that does not allow allele discrimination at higher resolution than two (2) digits.

The value in the data structure for a null allele shall be 0000.

MMMMMMMMMM shall be reserved for future use. A default value of 9999999999 shall be used at this time.

For information on printing bar code text, see 6.6.3.6, page 116.
For examples of use, see 8.5, page 122.

2.4.17 Container Manufacturer and Catalog Number [Data Structure 017]

Purpose: Data Structure 017 shall specify the manufacturer and catalog number of the container set and the identifying character(s) of the individual container(s) in the set.

Structure: =)bqqwwwwwww

Element	Length	Type
=	1	data identifier, first character
)	1	data identifier, second character
b	1	alphanumeric {A–Z; 0–9}
qq	2	alphanumeric {A–Z; 0–9}
wwwwwww	7	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **bqqwwwwwww** shall be encoded and interpreted as follows:

b shall specify the container identification character in a container or transfer set. The value of b is set as follows:
- For whole blood and other non-apheresis collection sets, 1-9 shall be used. 1 shall be reserved for the primary collection container
- for apheresis collection sets A-Z shall be used
- For transfer container/sets, 0 (zero) is used. If more than one type of container is present in the transfer set, numeric characters 2-9 may also be used. (The number 1 shall be reserved for the primary bag of a whole blood collection set.)

qq shall specify the identity of the container set manufacturer and is encoded and interpreted from Table W1, Manufacturer Identifier Codes (described in Section 3.2.2, page 91)

wwwwwww shall specify the manufacturer's catalog number. This shall be interpreted from information provided by the manufacturer. If the catalog number is less than seven (7) characters, it shall be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 0027QzE)

Used in conjunction with the Manufacturer's Data file (see Chapter 10, page 129 and *Implementation Guide, Use of the Manufacturers Data File*), this data structure can be a powerful tool for process control. With use of appropriate

software and downloading of the data file, much information about the container set can be determined automatically. This information includes the number of bags in the set, the anticoagulant/preservative, the intended nominal collection volume, etc.

2.4.18 Container Lot Number [Data Structure 018]

Purpose: Data Structure 018 shall specify the manufacturer's lot number for the container set.

Structure: &)xxxxxxxxxx

Element	Length	Type
&	1	data identifier, first character
)	1	data identifier, second character
xxxxxxxxxx	10	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **xxxxxxxxxx**, shall encode the manufacturer's lot number. If the lot number is less than ten (10) characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 1234rZ would be transmitted as 00001234rZ).

Because lot numbers can be padded with zeroes, ideally they should not begin with a 0 (zero). If the lot number begins with 0 (zero), the manufacturer shall have a mechanism to ensure correct identification of the lot number when a problem is reported and the lot number is indicated without the leading 0 (zero).

2.4.19 Donor Identification Number [Data Structure 019]

Purpose: Data Structure 019 shall specify a donor identification number that is unique anywhere in the world.

Structure: =;αppppvvvvvvvvvvvvvvv

Element	Length	Type
=	1	data identifier, first character
;	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A-N, P-Z, 0-9}, second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.
vvvvvvvvvvvvvvv	16	numeric {0–9}

The twenty-one (21)-character data content string, **αppppvvvvvvvvvvvvvvv**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) and is encoded and interpreted by reference to the ICCBBA Registered Facility table (see 4.3, page 97) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website

vvvvvvvvvvvvvvv shall specify either a nationally- or facility- assigned donor identification number. The interpretation of the assigned number requires knowledge of how such numbers are assigned in the country specified by the FIN. If the number assigned is not sixteen (16) characters, it shall be padded with zeroes at the beginning of the string (i.e., the donor identification number 395421746 would be transmitted as 0000000395421746). However, in some countries, the assigned number can begin with zero; therefore the specific length of the assigned number must be known in order to correctly interpret this data structure

2.4.19.1 Use of a National Donor Identification Number

If the Donor Identification Number is nationally-assigned using this data structure, a dedicated FIN can be assigned by ICCBBA to distinguish nationally- from facility-assigned numbers. To exercise this option, a

national authority should contact the ICCBBA office (tech.director@iccbba.org).

*Note: There is an alternative nationally-defined data structure that may be used for a donor identification number (*see *2.5.2, page 66).*

2.4.20 Staff Member Identification Number [Data Structure 020]

Purpose: Data Structure 020 shall specify a staff identification number.

Structure: ='αppppuuuuuu

Element	Length	Type
=	1	data identifier, first character
'	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
pppp	4	First two characters alphanumeric {A-N, P-Z, 0-9}, second two characters numeric {0–9}. Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.
uuuuuu	6	alphanumeric {A-Z, 0–9}

The eleven (11)-character data content string, **αppppuuuuuu**, shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) and shall be encoded and interpreted by reference to the ICCBBA Registered Facility table (see 4.3, page 97) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website

uuuuuu shall specify a facility-assigned staff member identification number. As noted above, the number may contain alphabetic characters if desired. If the string assigned is not six (6) characters, it shall be padded with zeroes at the beginning of the string (i.e., the staff member identification 395A would be transmitted as 00395A)

2.4.21 Manufacturer and Catalog Number: Items Other Than Containers [Data Structure 021]

Purpose: Data Structure 021 shall specify the manufacturer and the catalog number of an item used in collection or processing other than the container (set).

Structure: =-NNOOOOOOOO

Element	Length	Type
=	1	data identifier, first character
-	1	data identifier, second character
NN	2	alphanumeric {A–Z; 0–9}
OOOOOOOO	8	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **NNOOOOOOOO** shall be encoded and interpreted as follows:

NN shall specify the identity of the item manufacturer and is encoded and interpreted from Table W1, Manufacturer Identifier Codes (described in Section 3.2.2, page 91)

OOOOOOOO shall specify the manufacturer's catalog number. This shall be interpreted from information provided by the manufacturer. If the catalog number is less than eight (8) characters, it shall be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 00027QzE)

2.4.22 Lot Number: Items Other Than Containers [Data Structure 022]

Purpose: Data Structure 022 shall specify the manufacturer's lot number for an item used in collection or processing other than a container (set).

Structure: &-PPPPPPPPPP

Element	Length	Type
&	1	data identifier, first character
-	1	data identifier, second character
PPPPPPPPPP	10	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **PPPPPPPPPP**, shall encode the manufacturer's lot number. If the lot number is less than ten (10) characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 1234rZ would be transmitted as 00001234rZ).

Because lot numbers can be padded with zeroes, ideally they should not begin with a 0 (zero). If the lot number begins with 0 (zero), the manufacturer shall have a mechanism to ensure correct identification of the lot number when a problem is reported and the lot number is indicated without the leading 0 (zero).

2.4.23 Compound Message [Data Structure 023]

Purpose: Data Structure 023 shall allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems.

Structure: =+aabbb

Element	Length	Type
=	1	data identifier first character
+	1	data identifier second character
aa	2	numeric {0-9}
bbb	3	numeric {0-9}

The five-character data content string **aabbb** shall be encoded and interpreted as follows:

aa shall specify the number of ISBT 128 data structures that follow;

bbb shall be either:

- all zeros – indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is
- a three-digit number referencing an entry in an ICCBBA maintained table that defines the content of this structured compound message (see Table W2, Structured Compound Messages described in Section 3.2.3, page 91)

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 sequentially with no intervening characters, and each 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 an ICCBBA structured compound message format is used, the reference number of the structure shall be included in element bbb of the Compound Message Data Structure

6. If the message is not defined, the Compound Message Data Structure shall have element bbb set to zeros, and element aa shall be set as specified in rule 4

ICCBBA structured compound messages are defined in Table W2, Structured Compound Messages (described in Section 3.2.3, page 91). Requests for additional entries should be submitted to the ICCBBA office (tech.director@iccbba.org).

Unstructured messages should ONLY be used where there is not an appropriate structured message and there is good reason why a structured message should not be created. Unstructured messages should be used when a message structure is needed only temporarily (will only be used once or a few times). If there is any uncertainty whether a structured message should be created, the user should contact the ICCBBA office.

Reading software should always verify the integrity of the data string, including checking that the correct number of data structures appears. Data should only be interpreted if the integrity of the entire data string has been confirmed.

See 8.6, page 124, for an example of use.

2.4.24 Patient Date of Birth [Data Structure 024]

Purpose: Data Structure 024 shall indicate the date of birth of the patient and the location of this occurrence of the information.

Structure: =#aayyyymmdd

Element	Length	Type
=	1	data identifier, first character
#	1	data identifier, second character
aa	2	numeric {0–9}
yyyy	4	numeric {0–9}
mm	2	numeric { 0–9}
dd	2	numeric { 0–9}

The 10 character data content string, **aayyyymmdd**, shall be encoded and interpreted as follows:

aa shall specify a location code identifying where this occurrence of the information is held. For acceptable values see Table 17, page 86

yyyy shall specify the year of birth

mm shall specify the month of birth

dd shall specify the day of birth

See *Technical Bulletin 8: Specification for ISBT 128 Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification* for examples of use.

2.4.25 Patient Identification Number [Data Structure 025]

Purpose: Data Structure 025 shall indicate the patient identification number and the location of this occurrence of the information.

Structure: &#aallxx…xx

Note: This is a variable length structure – see *text below.*

Element	Length	Type
&	1	data identifier, first character
#	1	data identifier, second character
aa	2	numeric {0–9}
ll	2	numeric {0–9}
xx…xx	var	alpha/numeric { A-Z, a-z, 0–9}

The variable length data content string, **aallxx…xx**, shall be encoded and interpreted as follows:

aa shall specify a location code identifying where this occurrence of the information is held. For acceptable values see Table 17, page 86

ll shall specify the length of the following patient number field

xx…xx shall specify the patient identification number, alpha numeric only, punctuation characters and spaces are not permitted

Note: The patient identification number may only be unique within the facility in which it was assigned. There may be duplicate numbers if a patient moves from one facility to another.

Reading software should always verify the integrity of the data string, including checking that the correct number (as defined by ll) of characters appears in the patient identification number.

See *Technical Bulletin 8: Specification for ISBT 128 Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification* for examples of use.

2.4.26 Expiration Month and Year [Data Structure 026]

Purpose: Data Structure 026 shall indicate a month and year of expiration for supplies. This data structure should not be used for blood, tissue, or cellular therapy products.

Structure: =]yyyymm

Element	Length	Type
=	1	data identifier; first character
]	1	data identifier; second character
yyyy	4	numeric {0-9)
mm	2	numeric {0-9}

The six character data string **yyyymm** is encoded and interpreted as follows:

yyyy shall specify the year of expiration

mm shall specify the month of expiration

2.4.27 Infectious Markers [Data Structure 027]

Purpose: Data Structure 027 shall provide information on the infectious disease screening status of a product.

Structure: &"nnnnnnnnnnnnnnnnn

Element	Length	Type
&	1	data identifier, first character
"	1	data identifier, second character
nnnnnnnnnnnnnnnnn	18	numeric {0–9}

The 18 character data content string, **nnnnnnnnnnnnnnnnn**, shall be encoded and interpreted as follows:

nnnnnnnnnnnnnnnnn shall specify a string of digits, each of which shall identify the result status of a pair of markers as indicated in Table 18, page 87. Currently only values in the first nine positions have been defined; therefore positions 10-18 shall be set to a value of 0. For each marker there shall be three possible outcomes:

- pos Reactive for specified marker in screening process
- neg Specific marker not detected in screening process
- na Information not available

The information shall be specific to a particular donation and thus shall be provided in a manner that can be securely linked to the Donation Identification Number. This may be achieved by the use of a Compound Message structure containing both the Donation Identification Number and Infectious Marker screening, concatenated bar code reading, or by other mechanisms that secure association of the information.

The results provided in the data string shall be the final outcome of the approved screening process of the testing facility.

Generally, it is expected that this information will appear in electronic communications or accompanying documentation rather than on the affixed label of a product.

For an example of use for this data structure, see 8.7, page 125.

2.4.28 Product Consignment [Data Structure 028]

Purpose: Data Structure 028 shall transfer information about product shipments.

Structure: =&αppppyynnnnnccdd

Element	Length	Type
=	1	data identifier, first character
$	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
pppp	4	first two characters alphanumeric {A-N, P-Z, 0-9}, second two characters numeric {0–9}. (Current usage is numeric for all four characters. Alpha characters may be introduced into positions 1 and 2 in the future.)
yy	2	numeric {0-9}
nnnnn	5	numeric {0-9}
cc	2	numeric {0-9}
dd	2	numeric {0-9}

The sixteen character data string **αppppyynnnnnccdd** shall be encoded and interpreted as follows:

αpppp shall specify the Facility Identification Number (FIN) and is encoded and interpreted by reference to the ICCBBA Registered Facility table (see 4.3, page 97) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website

yy shall specify the year

nnnnn shall specify a serial number

cc shall specify the number of the container within consignment. For dispatch documentation (paper or electronic), this field shall be set to 00

dd shall specify the total number of containers in consignment

2.4.29 Dimensions [Data Structure 029]

Purpose: Data Structure 029 shall carry information about the dimensions (length, area, volume, etc.) of a product.

Structure: &$nnaabbbbccccccdee

Element	Length	Type
&	1	data identifier, first character
$	1	data identifier, second character
nn	2	numeric value (00-99)
		Repeating segments (repeats nn times):
aa	2	numeric value (0-9)
bbbb	4	numeric value (0-9)
ccccc	5	numeric value (0-9)
d	1	numeric value (0-9)
ee	2	numeric value (0-9)

The data content string, **nnaabbbbccccccdee**, shall be encoded and interpreted as follows:

nn Number of repeating segments

Repeating segment (repeats nn times):

aa Refers to a symbol as defined by Table 19, page 89

bbbb Refers to a dimension as defined by the Table 20, page 89

ccccc Value of the dimension specified in the associated product description code. Dimension values are in accordance with the limits of accuracy specified in the supplier's product catalog or product insert. Should the measured value be less than 5 characters, leading zeroes shall be used

d Number of decimal places as defined in Table 21, Page 89

ee Reserved for future use, set to 00 default

There is no requirement for the order in which dimensions may appear in the data string. Software shall be written to place a value in the appropriate field based on the value of aa and bbbb of the Dimensions Data Structure.

If the Dimensions Data Structure does not appear on an affixed label, it should be linked to the Donation Identification Number to which it corresponds. It is

strongly recommended that a Compound Message Data Structure [023] that incorporates both the DIN and Dimensions Data Structures be used (see 2.4.23).

If more than one dimension is conveyed and a linear bar code is used, the symbol may be too large to fit on the affixed label. In this situation, it is anticipated that this data structure will be used in electronic communication or on documents accompanying the product rather than on the container label.

Reading software should always verify the integrity of the data string, including checking that the correct number of repeat segments occurs. Data should only be interpreted if the integrity of the entire data string has been confirmed.

For examples of use and implementation guidance, see *Implementation Guideline, Dimensions [Data Structure 029]*, on the ICCBBA Website.

2.4.30 Red Cell Antigens with Test History [Data Structure 030]

Purpose: Data Structure 030 shall transfer information about red cell antigen phenotypes, including whether the test has been performed more than once and if the results represent current or historical data. It is anticipated that this data structure will be used in electronic communication or on documents accompanying the product rather than on the affixed label.

Structure: &%nnnpppppprrss

Element	Length	Type
&	1	data identifier, first character
%	1	data identifier, second character
nnn	3	numeric {0-9}
		Repeating segment (repeats nnn times):
pppppp	6	numeric {0-9}
rr	2	numeric {0-9}
ss	2	numeric {0-9}

The character data string **nnnpppppprrss** shall be encoded and interpreted as follows:

nnn Shall indicate the number of occurrences of the repeating segment in the data structure

Repeating segment (repeats nnn times):

pppppp ISBT-defined antigen as defined by the table described in 3.2.4, page 91

rr Result interpretation as defined by Table 22, page 90 (numeric, 0-9)

ss Number of tests as defined by Table 23, page 90 (numeric, 0-9)

There is no requirement for the order in which antigens may appear in the data string. Software shall be written to place an antigen in the appropriate field based on the value of pppppp.

When utilizing this data structure to express more than one test result, the results shall be concordant.

Information in the Red Cell Antigen with Test History Data Structure shall be firmly linked to the Donation Identification Number to which it corresponds. It is strongly recommended that a Compound Message Data Structure [023] that

incorporates both the DIN and the Red Cell Antigen with Test History Data Structures be used (see 2.4.23).

Reading software should always verify the integrity of the data string, including checking that the correct number of repeat segments occurs. Data should only be interpreted if the integrity of the entire data string has been confirmed.

For examples of use and implementation guidance, see *Implementation Guideline, Red Cell Antigen [Data Structure 030]*, on the ICCBBA Website.

2.5 Non-ICCBBA Defined Data Structures

2.5.1 Data Structures Not Defined by ICCBBA

Data structures that fit in the ISBT 128 model but are not internationally defined by ICCBBA may be desirable for use by individual facilities or by regional, national, or supranational authorities. The data identifiers &a through &z shall be reserved to support such data structures.

There should be a national consensus regarding which data identifiers should be reserved for national use and which, if any, should be allowed for regional or supranational use.

The facility identification numbers to which the definition of these data structure applies shall be documented and software shall only interpret these data structures within the context of those FIN(s).

Non-ICCBBA defined data structures shall not be used in Compound Messages.

Element	Length	Type
&	1	data identifier, first character
a-z	1	data identifier, second character
Further elements will be nationally (or regionally) defined.		

Note: Care should be taken not to confuse these non-ICCBBA defined data structures with locally- or nationally-assigned product codes (see Section 2.4.3, page 29).

Note: There are internationally defined data structures for nationally-defined Donor Identification Number [Data Structure 019] and Patient identification Number [Data Structure 025].

2.5.2 Reserved Data Identifiers for a Nationally-Specified Donor Identification Number

A nationally-specified data structure may be defined to contain a unique donor (not donation) identification number. The data identifier shall be "&;".

Element	Length	Type
&	1	data identifier, first character
;	1	data identifier, second character
Further elements will be nationally defined.		

Note: There is an alternative internationally-defined data structure that may be used for a donor identification number (see 2.4.19, page 49).

2.5.3 Confidential Unit Exclusion Status Data Structure

If desired, a nationally-specified structured bar code may be defined to contain the results of a confidential donor decision to request that a donated unit be either accepted for testing and processing or discarded. The data identifier shall be &!.

Element	Length	Type
&	1	data identifier, first character
!	1	data identifier, second character
Further elements will be nationally defined.		

3 Reference Tables

3.1 Reference Tables Maintained in This Document

Table 3 Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]

Value of ff	Meaning When Used in the Donation Identification Number
00	Flag not used; null value
01	Container 1 of a set
02	Container 2 of a set
03	Container 3 of a set
04	Container 4 of a set
05	Second (or repeated) “demand-printed” label
06	Pilot tube label
07	Test tube label
08	Donor record label
09	Sample tube for NAT testing
10	Samples for bacterial testing
11	Match with Unit label
12	Affixed partial label
13	Attached label (intended to be used with affixed partial label)
14	Reserved for future assignment
15	Container 5 of a set
16	Container 6 of a set
17	Container 7 of a set
18	Container 8 of a set
19	Container 9 of a set
20-59	Reserved for assignment and use by each local facility. Therefore the meaning and interpretation of flag values 20–59 may differ with each FIN and should not be interpreted at any other site
60–96	ISO/IEC 7064 modulo 37-2 check character on the preceding thirteen (13) data characters, **αppppyynnnnnn** including the FIN, year and the unit serial number — value is assigned as 60 plus the modulo 37-2 checksum
97–99	Reserved for future assignment

Table 4 Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Donation or Collection Information [RT005]

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
O RhD negative	95	91	92	93	94	96	97	98
O RhD positive	51	47	48	49	50	52	53	54
A RhD negative	06	02	03	04	05	07	08	09
A RhD positive	62	58	59	60	61	63	64	65
B RhD negative	17	13	14	15	16	18	19	20
B RhD positive	73	69	70	71	72	74	75	76
AB RhD negative	28	24	25	26	27	29	30	31
AB RhD positive	84	80	81	82	83	85	86	87
O	55	P2	P3	P4	P5	P7	P8	P9
A	66	A2	A3	A4	A5	A7	A8	A9
B	77	B2	B3	B4	B5	B7	B8	B9
AB	88	C2	C3	C4	C5	C7	C8	C9
para-Bombay, RhD negative	D6	D2	D3	D4	D5	D7	D8	D9
para-Bombay. RhD positive	E6	E2	E3	E4	E5	E7	E8	E9
Bombay, RhD negative	G6	G2	G3	G4	G5	G7	G8	G9
Bombay, RhD positive	H6	H2	H3	H4	H5	H7	H8	H9
O para-Bombay, Rh D negative	I6	I2	I3	I4	I5	I7	I8	I9
O para-Bombay, RhD positive	J6	J2	J3	J4	J5	J7	J8	J9
A para-Bombay, RhD negative	K6	K2	K3	K4	K5	K7	K8	K9

ABO and RhD Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous	Directed (Dedicated/ Designated) Collection/ Eligible for Crossover	Autologous Collection/ Eligible for Crossover	For Autologous Use Only	For Autologous Use Only/ Biohazardous
B para-Bombay, RhD negative	L6	L2	L3	L4	L5	L7	L8	L9
AB para-Bombay, RhD negative	M6	M2	M3	M4	M5	M7	M8	M9
A para-Bombay, RhD positive	N6	N2	N3	N4	N5	N7	N8	N9
B para-Bombay, RhD positive	O6	O2	O3	O4	O5	O7	O8	O9
AB para-Bombay, RhD positive	Q6	Q2	Q3	Q4	Q5	Q7	Q8	Q9

Table 5 Data Structure 002: Special Messages [RT006]

gg	Interpretation
A0	Group A, Pooled RhD [Pooled Products]
B0	Group B, Pooled RhD [Pooled Products]
C0	Group AB, Pooled RhD [Pooled Products]
D0	Group O, Pooled RhD [Pooled Products]
E0	Pooled ABO, RhD Positive [Pooled Products]
F0	Pooled ABO, RhD Negative [Pooled Products]
G0	Pooled ABO, Pooled RhD [Pooled Products]
H0	Pooled ABO (RhD not specified) [Pooled Products]
Ma	Autologous collection
Mb	Biohazardous
Md	Discard (to be destroyed)
Mf	For fractionation use only
Mq	Quarantine/hold for further testing or processing
Mr	For research use only
Mx	Not for transfusion based on test results
T1	RhD positive*
T2	RhD negative*
T3	RhD not specified*
T4	Autologous collection/in quarantine*
T5	See outer packaging for product status*
T6	Must be sterilized before release*

* Values in Table 5 that begin with the letter T (T1-T6) shall be used only with tissue products.

Table 6 Data Structure 002: Rh, Kell, and Mia/Mur Phenotypes [RT007]

Results with Anti-Kell:			**Results with:**			
Not tested	**Negative**	**Positive**	**Anti-C**	**Anti-c**	**Anti-E**	**Anti-e**
0	S	T	not tested	not tested	not tested	not tested
1	A	J	negative	positive	negative	positive
2	B	K	positive	positive	negative	positive
3	C	L	positive	positive	positive	positive
4	D	M	positive	positive	positive	negative
5	E	N	negative	positive	positive	positive
6	F	O	negative	positive	positive	negative
7	G	P	positive	negative	negative	positive
8	H	Q	positive	negative	positive	positive
9	I	R	positive	negative	positive	negative
X	Y	Z	negative	not tested	negative	not tested

U	Mi^a/Mur negative
V	Mi^a/Mur positive
W	Special Testing bar code present and must be scanned and interpreted

Values of **r** {0–9, A–T, X–Z} are used to encode the results of testing with anti-K, anti-C, anti-c, anti-E, and anti-e as shown in this table. (For example, if the value of **r** is **E**, then the red blood cells are K-negative, C-negative, c-positive, E-positive and e-positive). Values U and V encode Mi^a/Mur antigen test results.

Table 7 Data Structure 003: Type of Donation or Collection in 6th Position of Product Code [RT008]

Character	Type of Donation
0 (zero)	Not specified (null value)
V	Volunteer homologous (allogeneic) donor (default)
R	Volunteer research donor
S	Volunteer source donor
T	Volunteer therapeutic collection
P	Paid homologous (allogeneic) collection
r	Paid research collection
s	Paid source collection
A	Autologous collection, eligible for crossover
1 (one)	For autologous use only
X	For autologous use only, biohazard
D	Volunteer directed collection, eligible for crossover
d	Paid directed collection, eligible for crossover
2	For directed recipient use only
L	For directed recipient use only, limited exposure
E	For directed recipient use only, medical exception
Q	See (*i.e.*, read [scan]) Special Testing bar code
3	For directed recipient use only, biohazard
4	Designated collection
5	Dedicated collection
6	Designated collection, biohazard

Table 8 Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 1 Through 9 [RETIRED]

Position	**1**	**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**	
Antibody																	
Antigen / Value	**Rh**	**K**	**k**	**C^w**	**VS/V**	**A1**	**M**	**N**	**S**	**s**	**U**	**Mi^a†**	**P1**	**Lu^a**	**Kp^a**	**Js^a**	**Wr^a**
0	C+c-E+e-	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	C+c+E+e-	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	C-c+E+e-	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	C+c-E+e+	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	C+c+E+e+	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	C-c+E+e+	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	C+c-E-e+	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	C+c+E-e+	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	C-c+E-e+	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: † most commonly associated with GP.Mur (Mi.III); nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table 8 (continued) Data Structure 011**:** Special Testing: Red Blood Cell Antigens, Positions 10 Through 16 [RETIRED]

Position	**10**		**11**		**12**		**13**		**14**		**15**		**16**	
Antibody														**CMV**
Antigen / **Value**	**Le^{a}**	**Le^{b}**	**Fy^{a}**	**Fy^{b}**	**Jk^{a}**	**Jk^{b}**	**Di^{a}**	**Di^{b}**	**Do^{a}**	**Do^{b}**	**Co^{a}**	**Co^{b}**	**In^{a}**	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table 9 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 1 Through 9 [RT009]

Position	**1**	**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**	
Antibody																	
Antigen / **Value**	**Rh***	**K**	**k**	**C^w**	**Mi^a†**	**M**	**N**	**S**	**s**	**U**	**P1**	**Lu^a**	**Kp^a**	**Le^a**	**Le^b**	**Fy^a**	**Fy^b**
0	C+c-E+e-	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	C+c+E+e-	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	C-c+E+e-	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	C+c-E+e+	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	C+c+E+e+	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	C-c+E+e+	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	C+c-E-e+	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	C+c+E-e+	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	C-c+E-e+	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: † most commonly associated with GP.Mur (Mi.III); nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

*Common Rh antigens may be encoded together as a phenotype (Rh column 1) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column one shall be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens shall all be set to ni or NT.

Table 9 (continued) Data Structure 012: Special Testing: Red Blood Cell Antigens — Table General, Positions 10 Through 16

Position	**10**		**11**		**12**		**13**		**14**		**15**		**16**	
Antibody														**CMV**
Antigen / **Value**	**Jk^a**	**Jk^b**	**Do^a**	**Do^b**	**In^a**	**Co^b**	**Di^a**	**VS/ V**	**Js^a**	**C***	**c***	**E***	**e***	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: res — reserved; nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

*Common Rh antigens may be encoded together as a phenotype (Rh column 1) or as individual Rh antigens (C,c,E,e, columns 14-16). If Rh antigens are encoded individually using positions 14, 15, and/or 16, then the value of column one should be set to 9 (no information). Conversely, if the phenotype is present in column 1, then the values of the C,c,E,e antigens must all be set to ni or NT.

Table 10 Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 1 Through 9 [RT010]

Position	**1**	**2**		**3**		**4**		**5**		**6**		**7**		**8**		**9**	
Antibody																	
Antigen / Value	**Rh**	**K**	**k**	**C^w**	**Mi^a†**	**M**	**N**	**S**	**s**	**U**	**P1**	**Lu^a**	**Kp^a**	**Le^a**	**Le^b**	**Fy^a**	**Fy^b**
0	C+c-E+e-	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	C+c+E+e-	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	C-c+E+e-	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	C+c-E+e+	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	C+c+E+e+	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	C-c+E+e+	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	C+c-E-e+	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	C+c+E-e+	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	C-c+E-e+	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: † most commonly associated with GP.Mur (Mi.III); nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table 10 (continued) Data Structure 013**:** Special Testing: Red Blood Cell Antigens — Finnish, Positions 10 Through 16

Position	**10**		**11**		**12**		**13**		**14**		**15**		**16**	
Antibody														**CMV**
Antigen / **Value**	**Jk^{a}**	**Jk^{b}**	**Do^{a}**	**Do^{b}**	**C^{x}**	**Co^{b}**	**WES^{a}**	**LW^{b}**	**Ul^{a}**	**Ls^{a}**	**An^{a}**	**res**	**res**	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

Key: res — reserved; nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table 11 Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested and Found Negative [RETIRED]

Value	Antigen	Value	Antigen	Value	Antigen	Value	Antigen
00	see *Note*	25	Kp^b	50	Au^a	75	An^a
01	En^a	26	Kp^c	51	Au^b	76	Dh^a
02	'N'	27	Js^b	52	Fy4	77	Cr^a
03	V^w	28	Ul^a	53	Fy5	78	IFC
04	Mur	29	K11	54	Fy6	79	Kn^a
05	Hut	30	K12	55	removed	80	In^b
06	Hil	31	K13	56	Sd^a	81	Cs^a
09	hr^S	34	K18	59	Xg^a	84	Vel
10	hr^B	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At^a
12	Ce	37	K23	62	Sc3	87	Jr^a
13	G	38	K24	63	Jo^a	88	Ok^a
14	Hr_o	39	Lu^b	64	Do^b	89	reserved for future use
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	Ce	41	Lu4	66	Gy^a	91	reserved for future use
17	C^x	42	Lu5	67	Co3	92	reserved for future use
18	E^w	43	Lu6	68	LW^a	93	reserved for future use
19	D^w	44	Lu7	69	LW^b	94	reserved for future use
20	hr^H	45	Lu8	70	Kx	95	reserved for future use
21	Go^a	46	Lu11	71	Ge2	96	reserved for future use
22	Rh32	47	Lu12	72	Ge3	97	reserved for future use
23	Rh33	48	Lu13	73	Wb	98	IgA deficient
24	Tar	49	Lu20	74	Ls^a	99	Default

Note: When this data structure was retired, Table E3, to which value 00 referred, was also retired.

Table 12 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT011]

Value	Antigen	Value	Antigen	Value	Antigen	Value	Antigen
00	information elsewhere	25	Kp^b	50	Au^a	75	An^a
01	En^a	26	Kp^c	51	Au^b	76	Dh^a
02	'N'	27	Js^b	52	Fy4	77	Cr^a
03	V^w	28	Ul^a	53	Fy5	78	IFC
04	Mur*	29	K11	54	Fy6	79	Kn^a
05	Hut	30	K12	55	Di^b	80	In^b
06	Hil	31	K13	56	Sd^a	81	Cs^a
07	P	32	K14	57	Wr^b	82	I
08	PP_1P^k	33	K17	58	Yt^b	83	Er^a
09	hr^S	34	K18	59	Xg^a	84	Vel
10	hr^B	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At^a
12	Ce	37	K23	62	Sc3	87	Jr^a
13	G	38	K24	63	Jo^a	88	Ok^a
14	Hr_o	39	Lu^b	64	removed	89	Wr^a
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	Ce	41	Lu4	66	Gy^a	91	reserved for future use
17	C^x	42	Lu5	67	Co3	92	reserved for future use
18	E^w	43	Lu6	68	LW^a	93	reserved for future use
19	D^w	44	Lu7	69	LW^b	94	reserved for future use
20	hr^H	45	Lu8	70	Kx	95	reserved for future use
21	Go^a	46	Lu11	71	Ge2	96	Hemoglobin S negative
22	Rh32	47	Lu12	72	Ge3	97	parvovirus B19 antibody present
23	Rh33	48	Lu13	73	Wb	98	IgA deficient
24	Tar	49	Lu20	74	Ls^a	99	No Information Provided

Table 13 Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT012]

Value	Antigen	Value	Antigen	Value	Antigen	Value	Antigen
00	information elsewhere	25	Kp^b	50	Au^a	75	An^a
01	En^a	26	Kp^c	51	Au^b	76	Dh^a
02	'N'	27	Js^b	52	Fy4	77	Cr^a
03	V^w	28	Ul^a	53	Fy5	78	IFC
04	Mur*	29	K11	54	Fy6	79	Kn^a
05	Hut	30	K12	55	removed	80	In^b
06	Hil	31	K13	56	Sd^a	81	Cs^a
07	P	32	K14	57	Wr^b	82	I
08	PP_1P^k	33	K17	58	Yt^b	83	Er^a
09	hr^S	34	K18	59	Xg^a	84	Vel
10	hr^B	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At^a
12	Ce	37	K23	62	Sc3	87	Jr^a
13	G	38	K24	63	Jo^a	88	Ok^a
14	Hr_o	39	Lu^b	64	Do^b	89	Wr^a
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	Ce	41	Lu4	66	Gy^a	91	reserved for future use
17	C^x	42	Lu5	67	Co3	92	reserved for future use
18	E^w	43	Lu6	68	LW^a	93	reserved for future use
19	D^w	44	Lu7	69	LW^b	94	reserved for future use
20	hr^H	45	Lu8	70	Kx	95	reserved for future use
21	Go^a	46	Lu11	71	Ge2	96	reserved for future use
22	Rh32	47	Lu12	72	Ge3	97	reserved for future use
23	Rh33	48	Lu13	73	Wb	98	IgA deficient
24	Tar	49	Lu20	74	Ls^a	99	No Information Provided

Table 14 Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 Through 8 [RT013]

HLA-A	Value of AA	HLA-B	Value of BB
nt	00	nt	00
A1	01	B5	05
A2 A203 A210	02	B7 B703	07
A3	03	B8	08
A9	09	B12	12
A10	10	B13	13
A11	11	B14	14
A19	19	B15	15
A23	23	B16	16
A24 A2403	24	B17	17
A25	25	B18	18
A26	26	B21	21
A28	28	B22	22
A29	29	B27 B2708	27
A30	30	B35	35
A31	31	B37	37
A32	32	B38	38
A33	33	B39	39
A34	34	B40 B4005	40
A36	36	B41	41
A43	43	B42	42
A66	66	B44	44
A68	68	B45	45
A69	69	B46	46
A74	74	B47	47
A80	80	B48	48
ni	99	B49	49
		B50	50
		B51 B5102 B5103	51
		B52	52
		B53	53
		B54	54
		B55	55
		B56	56
		B57	57

HLA-A	Value of AA	HLA-B	Value of BB
		B58	58
		B59	59
		B60	60
		B61	61
		B62	62
		B63	63
		B64	64
		B65	65
		B67	67
		B70	70
		B71	71
		B72	72
		B73	73
		B75	75
		B76	76
		B77	77
		B78	78
		B81	81
		B82	82
		B83	83
		ni	99

nt — not tested; ni — no information

Table 15 Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 9 Through 16 [RT014]

Position	**9**		**10**		**11**		**12**		**13**		**14**		**15**		**16**	
Antibody																**CMV**
Antigen / Value	**HPA-1a**	**HPA-1b**	**HPA-2a**	**HPA-2b**	**HPA-3a**	**HPA-3b**	**HPA-4a**	**HPA-4b**	**HPA-5a**	**HPA-5b**	**HPA-6a**	**HPA-6b**	**HPA-7a**	**HPA-7b**	**IgA**	
0	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt	nt
1	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg
2	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos
3	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt	neg	nt
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt	pos	nt
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos
9	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni

nt — not tested; neg — negative; pos — positive; ni — no information (position not used)

Table 16 Data Structure 015: Special Testing: HLA-A and –B Alleles, Position 17 (CMV Antibody Status) [RT015] [RETIRED]

Value	CMV Antibody Status
0	nt
1	neg
2	pos

Table 17 Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number [RT018]

Value	Location
00	Not used
01	Wrist band
02	Order form
03	Sample Tube
04	Working list/Lab list/form
05	Test report
06	Delivery note/issue documentation
07	Intended recipient label (attached to container)
08	Label affixed to product
09-79	Reserved
80-99	For local or national use

Table 18 Data Structure 027: Infectious Markers: Positions 1 through 9 [RT019]

Position	1		2		3		4		5		6		7		8		9	
Antibody	HIV-1/2			HCV			HBc			HTLV-I/II	Syph-ilis	CMV				Parvo B19		Chagas
Antigen		HIV-p24			HCV			HBs										
Genome / Value			HIV			HCV			HBV				CMV	EBV	WNV		Parvo B19	
0	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
1	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg
2	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos
3	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na	neg	na
4	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg	neg
5	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos
6	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na	pos	na
7	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg	pos	neg
8	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos	pos

neg — negative; pos — positive; na — information not available

Table 19 (continued) Data Structure 027: Infectious Markers: Positions 10 through 18

Position	10		11		12		13		14		15		16		17		18	
Antibody																		
Antigen																		
Genome / Value																		
0	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na	na
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		

neg — negative; pos — positive; na — information not available

Note: Positions 10 through 18 have been reserved for future use.

Table 19 Data Structure 029: Symbols [RT037]

Value	Description
01	Dimension is equal to the expressed value within a tolerance defined by the facility
02	Dimension is greater than the expressed value
03	Dimension is greater than or equal to the expressed value
04	Dimension is less than the expressed value
05	Dimension is less than or equal to the expressed value
06	Dimension is the nominal value as defined within a circular of information/package insert for the product

Table 20 Data Structure 029: Dimensions [RT038]

Value	Units	Description
0001	Ml	Volume of the associated product including the anticoagulant/additive
0002	mm	Length of the associated product
0003	mm	Width of the associated product
0004	mm	Height of the associated product
0005	mm	Particle size of the associated product
0006	cm^2	Area of the associated product
0007	10E9	Total number of platelets in the container of the associated product
0008	g	Weight of associated product excluding the container but including the anticoagulant/additive
0009	g	Tare weight of container
0010	g	Tare weight of container and attached tubing

Table 21 Data Structure 029: Decimal Point [RT039]

Value	Meaning	Example
0	Integer value	12345
1	Decimal point between fourth and fifth numbers	1234.5
2	Decimal point between third and fourth numbers	123.45
3	Decimal point between second and third numbers	12.345
4	Decimal point between first and second numbers	1.2345
5	Decimal point is in the first position	.12345

Table 22 Data Structure 030: RBC Serological Results [RT040]

Value	Meaning
01	Negative
02	Positive

Table 23 Data Structure 030: Number of Tests [RT041]

Value	Meaning
01	Tested once on this donation
02	Tested once on prior donation
03	Tested ≥ twice on different donations (current and historic) with concordant results
04	Tested ≥ twice on different donations (historic only) with concordant results
05	Tested ≥ twice on this donation only, different samples, with concordant results

3.2 Reference Tables Maintained on Websites

3.2.1 Data Structures 015 and 016: HLA Genomic Typing

To encode for HLA-A, -B, and –DRB1 alleles, ISBT 128 utilized a database maintained by the European Bioinformatics Institute (EBI), which is part of the European Molecular Biology Laboratory (EMBL). This database provided for sequences of the human major histocompatibility complex (HLA) and included the official sequences for the WHO Nomenclature Committee for factors of the HLA System. The IMGT/HLA Database is part of the international ImMunoGeneTics project (IMGT).

Data Structures 015 and 016 have been retired as of this version of the *ISBT 128 Standard Technical Specification* (December 2011). The data structures were retired because they could not accommodate the increased number of characters required to encode HLA alleles that occurred in April 2010.

Continued use of Data Structures 015 and 016 should reflect terminology used prior to April 2010. The data structures cannot support newer antigens which require more than 4 characters. A crosswalk of allele names from their current name to the name prior to April 2010 may be found at:

ftp://ftp.ebi.ac.uk/pub/databases/imgt/mhc/hla/Nomenclature_2009.txt

3.2.2 Table W1 Data Structures 017 and 021: Manufacturer Identifier Codes [RT016]

This table is maintained on the ICCBBA Website at:

http://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables

3.2.3 W2 Data Structure 023 Structured Compound Messages [RT017]

This table is maintained on the ICCBBA Website at:

http://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables

3.2.4 Data Structure 030: Red Cell Antigens with Test History

This table is maintained by the Working Party on Red Cell Immunogenetics and Blood Group Terminology of the International Society of Blood Transfusion and posted at:

http://ibgrl.blood.co.uk/ISBTPages/ISBTHome.htm

4 Database Tables

In addition to the Reference Tables in Chapter 3, ICCBBA maintains ISBT 128 database tables using Microsoft Access® or Microsoft Excel®. These tables are too large and/or complex to be maintained as simple tables in this document.

A second format, as separate comma- or tab- delimited files, is provided for those who wish to use a different database program or who wish to download the databases into their own systems. These database tables are kept in the password-protected area of the ICCBBA Website and are only available to registered users who are current with their annual license fee.

4.1 Product Description Codes

There shall be a single ISBT 128 Product Description Code database for Blood Components, Cellular Therapy Products, Tissues, and Derivatives. Each group shall be distinguished by its group prefix character (E or F, S, T, and X, respectively) permitting individual tables to be extracted.

The Product Description Code forms the first five characters of the eight character Product Code Data Structure. A product in the ISBT 128 database shall be defined by a unique combination of the characteristics Class, Modifier, and Attribute(s). Each such combination shall be given a five character Product Description Code, the first character of which shall identify the product group (E, F, S, T, or X, as noted above), and the remaining four characters shall provide a unique sequence number. These codes shall be maintained in a table in the database named Product Description. The Product Description Code shall identify a product by mapping, via the Product Description table, to the unique combination of Class, Modifier, and Attribute(s) characteristics, which are referenced in the associated database tables.

Class and Modifier descriptions and their associated codes shall be maintained in a table in the database that is named Class. Attribute descriptions (including Core Conditions) and their associated codes shall be maintained in a table in the database named Attribute.

Version numbers for the database table shall be derived as described in Appendix B. The version of a database is maintained in a table named Version.

As noted above, all ISBT 128 database tables shall be published in the password-protected area of the ICCBBA Website. This file is a Microsoft Access® file and is named:

Product Description Codes Database – Access 2000

Comma-delimited text files of each of the tables in the Product Description Codes database (Text – Attribute, Text – Class, Text – Product Description Codes, and Text

Version) shall be provided on the ICCBBA Website to permit end-users to incorporate these tables into any preferred database application.

The structure of the database is described in the tables that follow.

More information about the Product Description Code database may be found in the following documents:

Product Code Structure and Labeling, Blood
Product Code Structure and Labeling, Cellular Therapy
Use of Product Code Data Structure [003], Tissues

Note: The Product Description Codes Database table structures are currently under review and are likely to change in the future. The proposal for change will be reviewed by the Technical Advisory Groups in the normal manner, and efforts will be made to minimize impact on users of these tables.

Table 24 CLASS Table [RT025]

Field	Field Type	Field Size	Description
NAMECODE	Text	3	Obsolete – Field is to be depopulated in the near future.
MODIFIER	Text	35	Modifier relates to a set of conditions that distinguishes members of the same component Class, *e.g.*, Washed, Frozen, *etc*.
CLASS	Text	36	The basic naming system adopted for products in ISBT 128
NAME	Text	75	The unique name produced by combining the Modifier and the Class
UNIQUE NAMECODE	Text	4	Unique identifier for the Class/Modifier of product
RETIREDATE	Text	11	Date on which it was recommended the code no longer be used for new products. The code is maintained in database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 25 ATTRIBUTE Table [RT026]

Field	Field Type	Field Size	Description
ATTRGRP	Text	1	Identifier for Attribute group.
ATTRVAR	Text	2	Identifier for Attribute variable within a group.
ATTRNAME	Text	50	Description of the Attribute group and variable (note: the group description is in the row with a variable value of zero).
ATTRFORM	Text	3	Obsolete – Field is depopulated.
UNIQUE ATTRFORM	Text	4	Unique identifier for the Attribute value combining the product type, Attribute group, and variable.
RETIREDATE	Text	11	Date on which it was recommended the code no longer be used for new products. The code is maintained in database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 26 PRODUCT DESCRIPTION Table [RT027]

Field	Field Type	Field Size	Description
PRODDESCRIPCODE	Text	5	The unique product description code for the product
NAMECODE	Text	3	Obsolete – Field is to be depopulated in the near future.
COMBATTRFORM	Text	60	Obsolete – Field is depopulated.
PRODDESCRIP0	Text	254	The description of the product in structured format
CODEDATE	Text	11	The date the code was assigned. Format is DD MMM YYYY.
PRODDESCRIP1	Text	254	Field available for national descriptions, not populated by ICCBBA
PRODCODEFORM	Text	50	Obsolete – Field is depopulated.
PRODDESCRIPCODEFORM	Text	65	Unique formula for the product comprising the Class description (corresponds to UNIQUE NAMECODE in the Class Table) and the combined Attribute codes (corresponds to UNIQUE ATTRFORM in the Attribute Table)
RETIREDATE	Text	11	Date on which it was recommended the code no longer be used for new products. The code is maintained in database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 27 VERSION Table (Product Description) [RT028]

Field	Field Type	Field Size	Description
Version Number	Text	50	The version number of the product database
Date	Text	11	The date issued. The format is DD MMM YYYY

4.2 Special Testing: General [Data Structure 010]

This database shall contain the test names and codes for data conveyed in Data Structure 10. It shall be published in the password-protected area of the ICCBBA Website. This file shall be a Microsoft Access® file and shall be named:

Special Testing General – Access 2000

A comma-delimited text file of the table in the Special Testing: General database (Special Testing General Text) shall also be provided to permit end-users to incorporate this table into any preferred database application.

Version numbers for the database table shall be derived as described in Appendix B.

Table 28 Special Testing: General [RT029]

Field Name	Field Size	Constraints	Field Description
NCODE	5	Primary key Required, no duplicates	UNIQUE ISBT 128 Special Testing Code
INTERPRETATION	200	Required, no duplicates	Information conveyed by the Special Testing Code
RETIREDATE	11		Date on which it was recommended that code no longer be used for new products. Code is maintained in the database for backward compatibility. Format is DD MMM YYYY. The field is blank for current codes.

Table 29 VERSION Table (Special Testing) [RT043]

Field	Field Type	Field Size	Description
Version Number	Text	50	The version number of the special testing database
Date	Text	11	The date issued. The format is DD MMM YYYY

4.3 Facility Identification Number Identification Code

This database shall contain the names and locations of all ICCBBA registered facilities. It is published in the password-protected area of the ICCBBA Website. This file shall be a Microsoft Excel® file and be named:

Registered Facilities – xls

It shall also be available on the Website as a tab delimited text file (Registered Facilities – Text).

Table 30 Registered Facilities [RT030]

Field Name	Field Size	Field Description
FIN	5	Facility Identification Number
Firm Name	60	Legal name of facility
City	30	Mailing address details of facility
State/Province	20	Mailing address details of facility
Country	20	Mailing address details of facility
Postal Code	10	Mailing address details of facility
Website	100	Website of the facility

5 Delivery Mechanisms for ISBT 128 Data Structures

ISBT 128 data structures can be delivered using a number of different technologies including linear bar codes, two-dimensional (2-D) bar codes, wireless radio frequency identification transponders (RFID tags), and EDI messages. Rules for such uses of ISBT 128 data structures will depend on the delivery mechanism.

5.1 Linear Symbols

5.1.1 General Requirements

ISBT 128 data structures represented as linear bar codes shall use Code 128 symbology and be compliant with ISO/IEC 15417. Implementers shall ensure that a switch can be made to subset C of the Code 128 symbology where appropriate in order to reduce bar code length.

5.1.2 Symbol Print Quality

As described in ISO/IEC 15416, print quality of a Code 128 symbol 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 the ANSI standard X3.182 – 1990.

5.1.3 Symbol Dimensions

Nominal module width (X): The X dimension shall be constant throughout a given symbol. The X dimension is the width of the narrowest bar within the bar code symbol.

Whenever possible, ISBT 128 bar codes used on a container label should be printed using a nominal X dimension of 0.25 mm, and in no case shall they be printed at a nominal X dimension smaller than 0.17 mm.

Note: Printers and scanners need to be compatible with the X dimension selected.

Any use of an ISBT 128 data structure as a linear printed bar code (i.e., not only on container labels, but on test tubes, etc.) should use an X dimension that meets these criteria.

Non-ICCBBA defined bar codes (such as national use bar codes) used on blood labels should meet the criteria listed above.

Bar Code Quiet Zones: The minimum width of a quiet zone shall be 10X.

A “quiet zone” is the clear space preceding the start character of the bar code and that following the stop character. This quiet zone is essential for the reading of the symbol.

There shall be no printing in direct contact with the top and bottom of the bar code.

Bar Code Height: In accordance with the recommendation in Annex G of ISO/IEC 15417, the bar code height shall be at least 5 mm or 15% of the symbol length, whichever is greater, on product labels that will leave the facility in which the products were labeled. For bar codes on labels or documents that will not leave the facility in which they were created, users should validate the minimum height of a label that can be read with their scanning equipment and ensure labels meet this internal requirement.

Concatenated Bar Codes: For linear bar codes that may be concatenated, the distance between the two bar codes shall fall within the specified range (see Chapter 9).

5.2 2-D Symbols

5.2.1 General Requirements

Data Matrix (ECC 200) shall be used as the 2-D symbology for ISBT 128 container labels. The ISO/IEC 16022 Information technology—International symbology specification—Data Matrix shall be followed.

For applications of ISBT 128 other than container labels, Data Matrix is recommended.

5.2.2 Symbol Quality

As 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 the ANSI standard X3.182 – 1990.

5.2.3 Symbol Dimensions

X dimension: The nominal X dimension shall be a minimum of 0.25 mm and a maximum of 1 mm. Within these criteria, as large an X dimension as practical should be used.

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 shall be 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.

5.2.4 Reading and Interpreting Information

Software should be written to ensure that the full data string matches the information provided in the Compound Message data structure and Table W2, Structured Compound Messages described in Section 3.2.3, page 91.

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 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.

For further information on implementation of 2-D symbols, see Implementation Guide: *Use of Data Matrix symbols with ISBT 128*.

5.3 RFID Tags

Use of RFID technology for blood components should comply with the guidelines published in Vox Sanguinis [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]. These guidelines recommend:

- The use of passive HF (13.56 MHz)
- That the user follow ISO 18000-3 tag standard and the ISO 15961 and ISO 15962 data encoding rules.
- That ISBT 128 data structures be used within the message.

Additional guidance will be provided as this technology develops.

5.4 EDI Messages

Rules for incorporating ISBT 128 data structures into EDI messages will normally be specified by the body responsible for the message standard. The only restriction placed by ICCBBA is that data identifier characters are a required part of the data field unless the message standard provides an alternative means of unambiguously identifying a data field as containing a specific ISBT 128 data structure, in which case they may be omitted.

For messages following the HL7 Standard, see Chapter 11.

6 Product Labeling

6.1 Tissue Labeling

This chapter applies to blood and cellular therapy products. For information on labeling tissue products, see *ISBT 128 Standard Labeling of Human Tissues*.

6.2 National Labeling Guidelines

National bodies may publish guidelines for labeling which adhere to the ISBT 128 Standard, as well as the rules set forth in the *ISBT 128 Standard Product Code Structure and Labeling* documents (Cellular Therapy and Blood Components). ICCBBA maintains on its Websites examples of such national documents. For assistance in creating such national guidelines, or to share a national guideline on the ICCBBA Website, contact the ICCBBA office (tech.director@iccbba.org).

6.3 General Principles

Two label general types are specified in ISBT 128: The label applied by the manufacturer of the container referred to as the base label and the label placed on a product container by the processing facility referred to as the final label.

The following general principles apply to label design:

Primary considerations in label design shall include improving the safety of the product and the efficiency of processing/administering. If these two considerations conflict, safety shall take precedence over efficiency.

Critical information on the container shall dominate the label via position and prominence and shall take precedence over information that is of little importance to the end-user (clinician, nurse, laboratory staff, and other hospital personnel).

6.4 Base Label Bar Code Placement

6.4.1 Standard Base Label Bar Code Placement

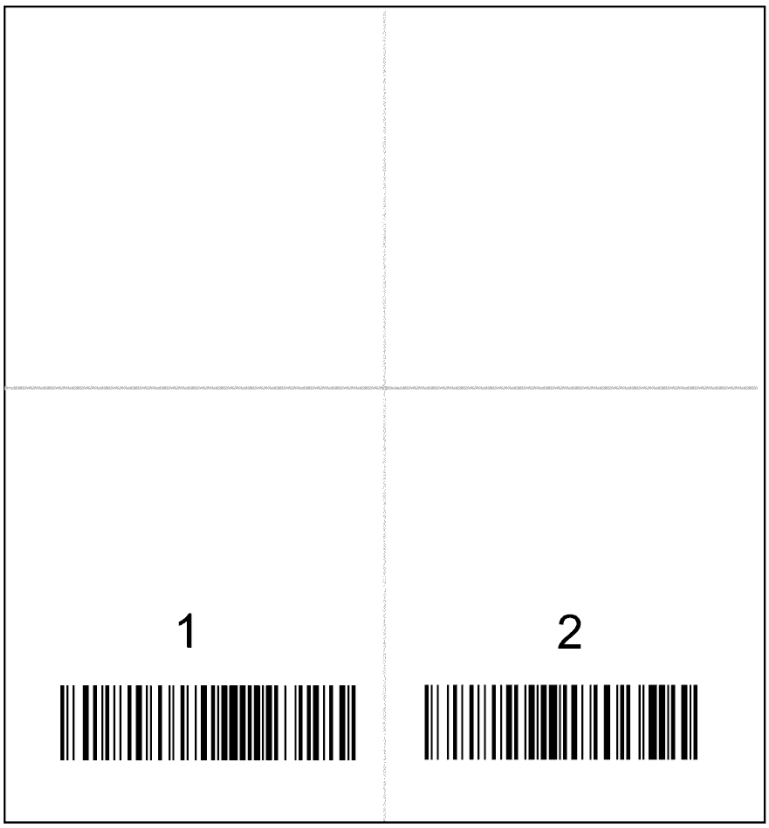
Where the container is of sufficient size, it shall carry a 100 ± 2 mm by 106 ± 2 mm base label.

The base label should carry the two manufacturer's information bar codes: the Container Manufacturer and Catalog Number [017] bar code in the lower left quadrant and the Manufacturer's Lot Number [018] bar code in the lower right quadrant. The recommended position for these bar codes on 100 ± 2 mm by 106 ± 2 mm label is indicated in Table 31, page 103.

Table 31 Positioning Bar Codes on the Base Labels [RT020]

Bar Code	Vertical Alignment	Horizontal Alignment
Container Manufacturer and Catalog Number [017]	3 mm from bottom of Left Quadrant [or 9 mm from bottom of label]	Bar code right edge should be at 4 mm from right edge of Left Quadrant
Container Lot Number [018]	3 mm from bottom of Right Quadrant [or 9 mm from bottom of label]	Bar code left edge should be at 4 mm from left edge of Right Quadrant

Figure 5 Placement and Nominal Size of Bar Codes on Base Label



Required Bar Codes
1 – Container Manufacturer and Catalog Number
2 – Container Lot Number

Gray lines are for reference only and should not be printed on the label

6.4.2 Small Base Label Bar Code Placement

The size of some containers does not allow a 100 ± 2 mm by 106 ± 2 mm base label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

An alternative label design may be used if the container will accommodate a 50 mm x 75 mm label. This base label shall carry the two manufacturer's information bar codes. The Container Manufacturer and Catalog Number [017] bar code shall be printed vertically in the upper half of the label and the Manufacturer's Lot Number [018] shall be printed vertically in the lower half of the label. The recommended position for these bar codes is indicated in Table 32, and is illustrated in Figure 6, page 105. This places the bar codes in an ideal position for concatenation.

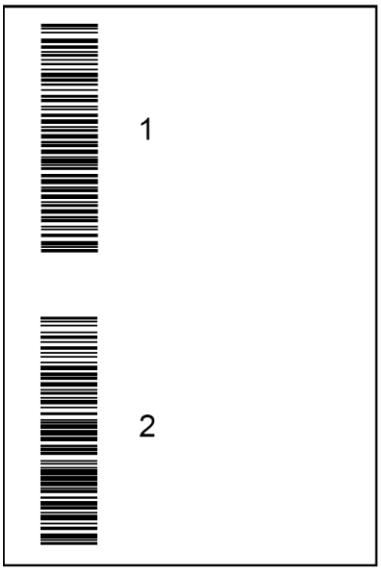
In order to accommodate the smaller size of the 50 mm x 75 mm label, and allow for concatenation of the bar codes, an X dimension as small as 0.17 mm may be used. Users should ensure that scanners selected will be able to accommodate this X dimension.

The bar code height may also be reduced to equal or greater than 15% of the bar code length (e.g., reduced to approximately 7 mm if the bar code is approximately 43 mm) in order to accommodate required text.

Table 32 Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]

Bar Code	From vertical center of label	From left side of label
Container manufacturer and catalog number	The right edge of the bar code is 4 mm above the vertical center of the label	Lower edge of the bar code is 6 mm from the left side of the label
Lot number	The left edge of the bar code is 4 mm below the vertical center of the label	The lower edge of the bar code is 6 mm from the left side of the label

Figure 6 Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm Base Label



1 – Container Manufacturer and Catalog Number
2 – Container Lot Number

6.5 Final Label Bar Code Placement

6.5.1 100 mm by 100 mm Final Label

The default size of the final label is 100 (+/-2) mm by 100 (+/-2) mm. Where the container size does not support this size of label, special consideration will need to be given (see 6.5).

The final label may be applied as a single 100 mm x 100 mm label or may be built up with smaller labels applied at different stages during the process.

The final label design shall be based upon the concept of four equal 50 (+/-1) mm by 50 (+/-1) mm quadrants. The bar codes shall be placed in these quadrants as shown in Table 33 on page 107.

Linear bar codes for Data Structures 001, 002, 003 and 005 shall be present and positioned as described in Table 33, page107 and Table 34, page 107. These requirements place the bar codes in an ideal position for concatenation.

Linear bar codes for other Data Structures found on the final label, and the Data Matrix symbol, should be positioned as described on Table 35, page 107.

Blood labels: When present, the Data Matrix symbol shall include the four data structures (DIN, Product Code, ABO/RhD, and Expiration Date and Time) required for linear bar codes. Additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Cellular therapy product labels: The Data Matrix symbol shall include the DIN and Product Code. If known and pertinent, the ABO/Rh shall be included. The expiration date (if it exists) shall be present. Additional ISBT 128 data structures (excluding nationally defined structures) may also be included.

Figure 7, page 108, shows final label printed according to these tables.

Table 33 Final Label Quadrants and Bar Codes [RT022]

Quadrant	Data Structure [Reference number]
Upper Left	Donation Identification Number (required) [001]
	Collection Date and Time (optional) [006, 007] or Production Date and Time (optional) [008, 009]
Lower Left	Product Code (required) [003]
	Dimensions (optional) [029]
Upper Right	ABO/RhD Blood Group (required) [002]
Lower Right	Expiration Date and Time (required for blood) [005]
	Special Testing (optional) [010,011,012,013,014,015,016]
	Data Matrix (2-D) symbol

Table 34 Required Positioning of Bar Codes on Final Labels [RT023]

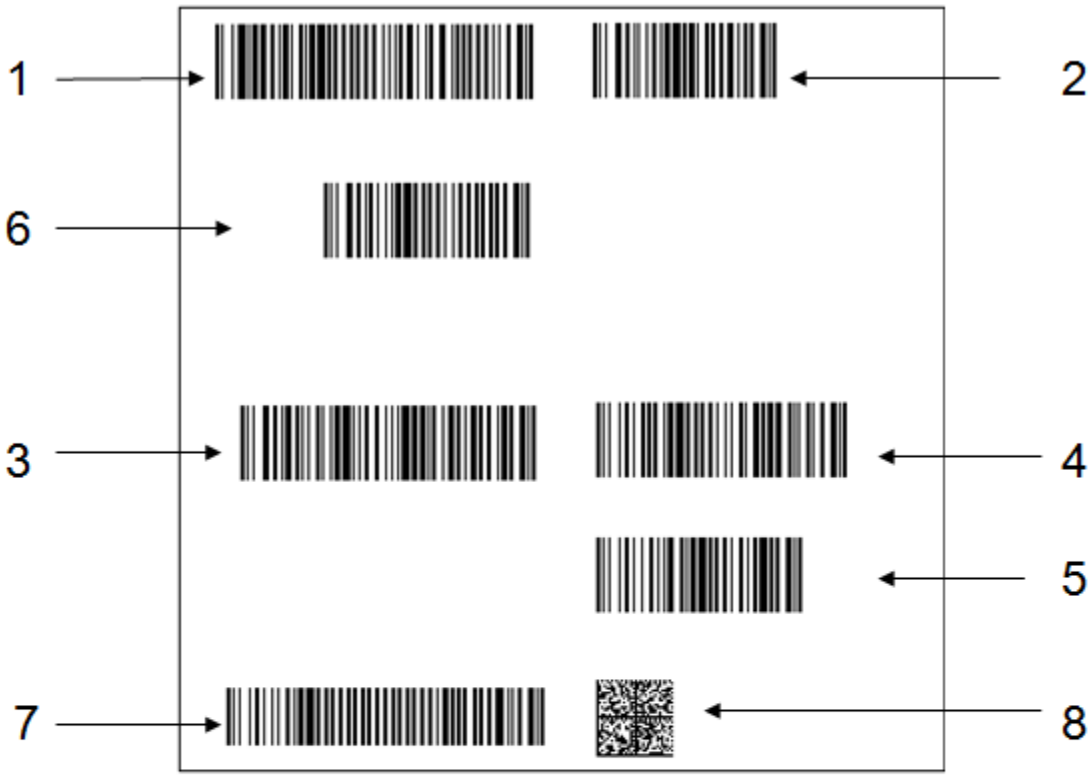
Bar Code	Vertical Alignment	Horizontal Alignment
Donation Identification Number [001]	3 mm from top of Upper Left Quadrant	Bar code right edge should be 4 mm from right edge of Upper Left Quadrant
Product Code [003]	3 mm from top of Lower Left Quadrant	Bar code right edge should be 4 mm from right edge of Lower Left Quadrant
ABO/RhD Blood Groups [002]	3 mm from top of Upper Right Quadrant	Bar code left edge should be 4 mm from left edge of Upper Right Quadrant
Expiration Date (and Time) [005]	3 mm from top of Lower Right Quadrant	Bar code left edge should be 4 mm from left edge of Lower Right Quadrant

Table 35 Recommended Positioning of Bar Codes on Final Labels [RT024]

While these barcodes shall be placed in the quadrants indicated, their exact placement within the quadrant is not mandated.

Bar Code	Vertical Alignment	Horizontal Alignment
Collection Date (and Time) [006, 007] or Production date (and Time) [008, 009]	20 mm from top of Upper Left Quadrant	Bar code right edge should be at 4 mm from right edge of Upper Left Quadrant
Special Testing [one of several alternative data structures]	20 mm from top of Lower Right Quadrant	Bar code left edge should be at 4 mm from left edge of Lower Right Quadrant
Dimensions [029]	As close to the bottom of the label as practical	Bar code right edge should be at 4 mm from right edge of Lower Left Quadrant
Data Matrix symbol	As close to the bottom of the label as practical	Not specified.

Figure 7 Placement and Nominal Size of Bar Codes on Final Label



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

Optional Bar Codes and Symbols
5 – Special Testing
6 – Collection (or Production) Date or Date and Time
7 – Dimensions
8 – Data Matrix symbol

To assist in label design, if more than one linear bar code is to be placed in a quadrant, e.g., Expiration Date and Special Testing, some adjustment of the absolute position of bar codes other than those for Data Structures 001, 002, 003 and 005 is permissible. Additionally, depending on the amount of text that is required, it may be necessary to reduce bar code height in accordance with bar code height requirements described 5.1.3, beginning on page 98.

A library of example labels from different countries is posted on the ICCBBA Website.

6.5.2 Small Final Label

Some containers may require a smaller final label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

If the design includes use of linear bar codes with an X dimension of <0.25 mm, care should be taken to ensure that all scanners that will be used to read the label are able to do so.

At a minimum,

1) Every ISBT 128-labeled product shall carry an electronically readable Donation Identification Number and Product Code
2) Every ISBT 128-labeled product shall carry an eye-readable text Donation Identification Number and Product Code
3) These (1 and 2 above) should appear on the affixed label whenever possible
4) If linear bar codes are used and the affixed label is too small to carry both bar codes, then the DIN bar code shall appear on the affixed label, along with eye-readable DIN and Product Code text. The DIN and Product Code bar codes shall also be carried together on an attached label or on accompanying documentation (*Note: For traceability, both the ISBT 128 DIN and Product Code, which includes both the Product Description Code and the division/pack code, are required.)*

6.6 Printing Label Text

6.6.1 Eye-Readable Text for Linear Bar Codes

The eye-readable text is the representation of the data characters in a bar code that is printed left justified immediately below a linear bar code, unless otherwise specified (see Figure 10, page 146).

Every Code 128 bar code on a container label shall be accompanied by eye-readable text. Bar code data identifiers are non-data characters and therefore shall appear only in the bar codes, not in the eye-readable text.

6.6.1.1 Donation Identification Number [001]

The eye-readable text for a Donation Identification Number is unique in that it is the sole means of presenting the data content of the bar code, i.e., it serves the dual role of eye-readable text and bar code text. As bar code text it shall be printed using a sans serif typeface. A national authority should determine how it should be displayed, for example:

V0043 99 499999

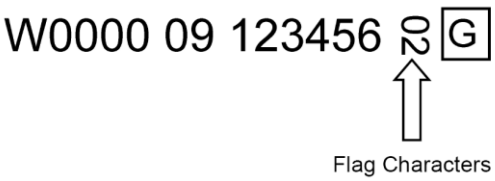
7004 203 123 456

All data characters shall be printed (in this instance only, the second data identifier character is also a data character).

The flag characters "ff" may be used to convey specific information other than the unique identification of the product and shall be distinguished from the Donation Identification Number (see 2.4.1).

When Type 1 or Type 2 flag characters are used (see page 25) they shall be printed as either:

- Numeric Presentation: The two-digit values of flags "ff" shall be printed rotated 90° clockwise to make them visually different from the Donation Identification Number.



- Non-numeric Presentation: A graphical icon or other representation of the value of "ff", e.g., for flag "07" printing an icon showing a small test tube.

Type 3 flag characters (see page 25) shall not be printed.

6.6.1.2 Container Manufacturer and Catalog Number [017] and Container Lot Number [018]

When these bar codes are printed on the 100 mm by 106 mm base label, eye-readable text shall be printed in sans serif type in the 6 mm segment of the base label that will remain visible after the application of the final label. The height of this text shall not exceed 3 mm. It shall be centered vertically within the segment (see Figure 13, page 154) and commence in line with the leftmost bar of the bar code.

When these bar codes are printed on smaller base labels, the eye-readable text for these two bar codes shall be printed left justified

immediately below the bar code. The eye-readable text should remain visible after the base label is over-labeled with the final label. See Figure 14, page 155.

6.6.1.3 All Other Bar Codes

Eye-readable text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code and be represented in sans serif type with a maximum height of 2 mm (see Figure 10, page 146).

6.6.2 Keyboard Entry Check Character K

A keyboard entry check character **K** shall be used when eye-readable text appears in conjunction with the following data structures in order to verify correct manual entry of the data content:

- Donation Identification Number [001]
- Special Testing: Red Blood Cell Antigens [011]
- Special Testing: Red Blood Cell Antigens — General [012]
- Special Testing: Red Blood Cell Antigens — Finnish [013]
- Special Testing: Platelet HLA and Platelet-Specific Antigens [014]
- Special Testing: HLA-A and –B Alleles [015]
- Special Testing: HLA-DRB1 Alleles [016]
- Donor Identification Number [019]
- Infectious Marker [027]

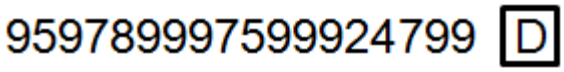
In the case of Data Structure 001 [Donation Identification Number], the calculation shall be based on the Donation Identification Number only, i.e., excluding the flag characters.

For other bar codes, the keyboard entry character may be used (see Table 36, page 112). Because the ISO/IEC 7064 modulo 37-2 checksum method does not allow for lower case alpha characters, it shall not be used in data structures that have lower case alpha characters.

K is not part of the data content string but is calculated from it using the ISO/IEC 7064 modulo 37-2 checksum method. **K** is a character in the range {A-Z, 0-9, *} determined from the modulo 37 remainder of the weighted sum of the data content string as shown in Table 42 in Appendix A. For an example of the calculation for the 13-character string **αppppyynnnnnn** of the Donation Identification Number see Appendix A.

Wherever the keyboard check character is printed, it shall be clearly distinguished from data content. When printed in association with the eye-readable text of a code, a box shall be drawn around the keyboard entry check character.

For example, a Red Cell phenotype would be printed:



Because of the significance of this particular character, it shall be printed in a typeface that clearly distinguishes alphabetic and numeric characters; e.g., there shall be no confusion between 1 (one) and I (capital letter I), or between 0 (zero) and O (capital letter O).

Table 36 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002]

Ref	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
001	Donation Identification Number	Required
002	Blood Groups [ABO and RhD]	Not applicable
003	Product Code	Not applicable
004	Expiration Date	Optional
005	Expiration Date and Time	Optional
006	Collection Date	Optional
007	Collection Date and Time	Optional
008	Production Date	Optional
009	Production Date and Time	Optional
010	Special Testing: General	Optional
011	Special Testing: Red Blood Cell Antigens (retired)	Required
012	Special Testing: Red Blood Cell Antigens — General	Required
013	Special Testing: Red Blood Cell Antigens — Finnish	Required
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	Required
015	Special Testing: HLA-A and –B Alleles (RETIRED)	Required
016	Special Testing: HLA-DRB1 Alleles (RETIRED)	Required
017	Container Manufacturer and Catalog Number	Not applicable
018	Container Lot Number	Not applicable
019	Donor Identification Number	Required
020	Staff Member Identification Number	Optional
021	Manufacturer and Catalog Number: Items Other Than Containers	Not applicable
022	Lot Number: Items Other Than Containers	Not applicable

Ref	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
023	Compound Message	Not applicable
024	Patient Date of Birth	Optional
025	Patient Hospital Identification Number	Not applicable
026	Expiration Month and Year	Optional
027	Infectious Markers	Required
028	Product Consignment	Optional
029	Dimensions	Optional
030	Red Cell Antigens with Test History	Not Applicable

6.6.3 Bar Code Text

Bar code text is the interpretation of the eye-readable text (the data content of the bar code) in terminology meaningful to the user (see Figure 10, page 146). Bar code text is nationally defined to allow for differences in language, regulatory requirements, and preferences.

Particular font sizes and types are not specified for bar code and additional text but designers shall ensure clarity of all text and use larger fonts to emphasize critical information. The font chosen should clearly differentiate between similar characters (e.g., O and 0; I and 1). Sans serif fonts shall be used for Latin alphabets. The use of color (for example, for ABO) is neither prohibited nor encouraged.

Bar code text corresponding to information content of electronically readable information shall appear on the label. If the size of the label does not support the information content required by this standard, appropriate regulations and requirements of standard setting organizations should be consulted. Some required information may need to appear on secondary packaging.

6.6.3.1 Blood Groups [ABO and RhD] [Data Structure 002]

ABO status may be printed black on white if RhD positive, outline black on white if RhD negative, but this is not required.

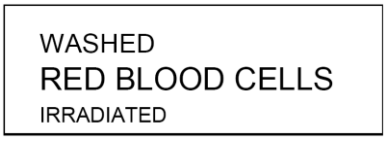
RhD status for the Blood Groups [ABO and RhD] bar code text may be printed black on white if RhD positive; white on black if RhD negative, but this is not required.

6.6.3.2 Product Descriptions [Data Structure 003]

Where space permits, the Class, Modifier, and Attributes (except default Attributes) text shall be printed on the label.

Product description bar code text should be printed with the Modifier proportionally smaller than the Class proper name and Attribute(s) text should be proportionately smaller than Modifier text.

Figure 8 Relative Text Size of Class, Modifier, and Attributes



6.6.3.3 Dates [Data Structures 004, 005, 006, 007, 008, 009, 024]

Dates shall be printed in compliance with ISO 8601-2004 extended format or in the format day — month — year. In the latter case, the day shall be numerical, the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

Expiration Date:

2011-03-17

OR

17 MAR 2011

Note: Abbreviations for month shall comply with relevant national standards where applicable.

Times shall be printed based on a twenty-four hour clock with a colon placed between the hours and minutes.

For Cellular Therapy products with text expiration times, time zones shall be taken into consideration. If the product is to be shipped across time zones, FACT and JACIE Standards require that the text expiration date and time include the local time zone abbreviation. In addition, the ISBT 128 Standard requires that the label include the Universal Coordinated Time (UTC) when the product is to be shipped across an international time zone.

The UTC shall be printed beneath the local time in parenthesis with the designation “UTC”. Italics may also be used to clearly differentiate UTC from local time. For example:

Expiration Date/Time:

15 JAN 2011 15:15 EST
(15 JAN 2011 20:15 UTC)

OR

2011-01-15 15:15 EST
(2011-01-15 15:15 UTC)

Note: It is recognized that local time zone designations may have little meaning internationally since two time zones may have the same abbreviation (e.g., EST can mean Eastern Standard Time in Australia, which is UTC+10 hours or Eastern Standard Time in North America, which is UTC -5 hours). However, the Cellular Therapy Coding and Advisory Group (CTCLAG) believe that local time zones are more readily interpreted within a continent. For products shipped to different continents, UTC should be used to interpret time.

6.6.3.4 Month-Year [Data Structure 026]

The date shall be printed in compliance with ISO 8601-2004 extended format or in the format month — year. In the latter case, the month alphabetical expression shall use a three-letter abbreviation. The year shall be a four-digit numerical representation.

2011-03

OR

MAR 2011

Note: Abbreviations for month shall comply with relevant national standards where applicable.

6.6.3.5 Special Testing, Red Blood Cell Antigens [Data Structures 011, 012, and 013]

National guidelines should be consulted for specific information regarding the printing of this bar code text. As an example, rather than the complete red blood cell phenotype associated with Data Structure 012, the bar code text may read:

Phenotype provided in
accompanying documentation

or some similar phrase. Alternatively, the antigen profile relevant to the recipient may be emphasized with the notation that the remainder of the interpretation of the bar code is presented elsewhere.

6.6.3.6 Special Testing: HLA-A and –B Alleles [Data Structure 015] and Special Testing: HLA-DRB1 Alleles [Data Structure 016]

Note: These data structures have been retired

If alleles are determined genomically, the bar code text allele numbers shall be preceded by an asterisk (*).

HLA-A*0103,0201;B*0702,2705
DRB1*03,15

A null allele shall be represented by a — (dash) in the bar code text.

HLA-A*0301,—;B*0702,0801
DRB1*0301, —

6.6.3.7 Donor Identification Number [Data Structure 019]

When the Donor Identification Number is less than 16 digits, it shall be padded with zeros at the beginning of the actual number. If desired, software developers can routinely strip off padding and present the actual number when printing the number or displaying the number on a screen.

For example:

In Denmark, a possible data content string would be:

000000 080656 1665

a ten (10)-digit number with six (6) leading zeroes as padding. This number might display on a screen as **080656 1665.**

In France, it might be:

0 1 56 05 18 033 087 78

a fifteen (15)-digit number with a single (1) leading zero as padding. This number might display on the screen as **1 56 05 18 033 087 78.**

7 Outer Package Labeling for Containers and Supplies

Outer cartons containing collection containers or other supplies should be marked for electronic data capture using bar coded information in accordance with the GS1 standard. At a minimum the information encoded should include (GS1 Application Identifier shown in parentheses):

- Global Trade Item Number (01);
- Batch or Lot Number (10);
- Expiration Date (17).

According to GS1 recommendations, this information should be carried in a GS1-128 barcode placed on the carton. GS1 general specifications give full detail about the data structure and the encryption into the barcode. The following example illustrates how the information is carried in a GS1-128 barcode.

Figure 9 GS1 Outer Packaging Bar Code

Technical Bulletin 9 Blood Bag Identification Using ISBT 128 and GS1, which is available on the ICCBBA Website, provides guidance to blood bag manufacturers, their customers, and software developers on the bar coding of blood bags and their shipping containers. It deals with the relationship between information held in the GS1 carton codes and the ISBT 128 blood container label codes and recommends ways to simplify the mapping of this information.

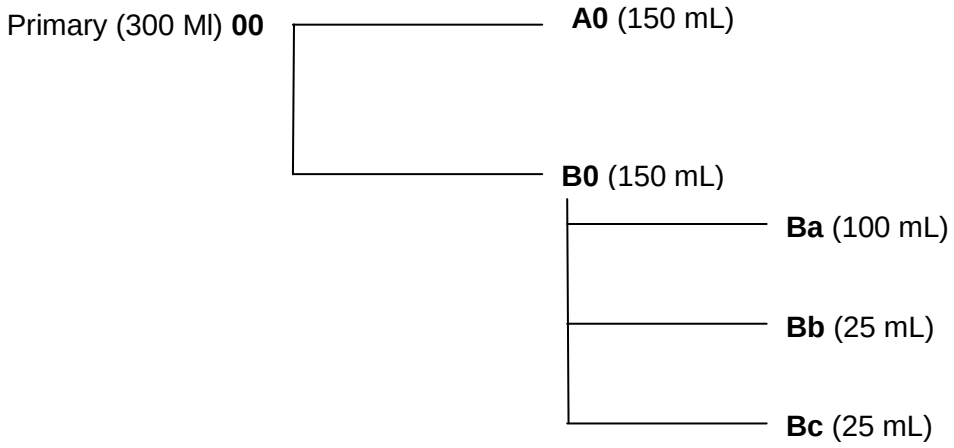
8 Data Structure Coding and Decoding: Examples of Use

8.1 Data Structure 003 Product Code: Coding of Blood and Cellular Therapy Products That Have Been Divided

Units made by the division of a single container of a product into two or more parts that are identical except for volume are “divided units.” For blood and cellular therapy products, such units shall have the same Donation Identification Number and may have the same first six data characters of the Product Code. Two separate divisions (ds) can be coded in the seventh and eighth positions of the Product Code Data Structure.

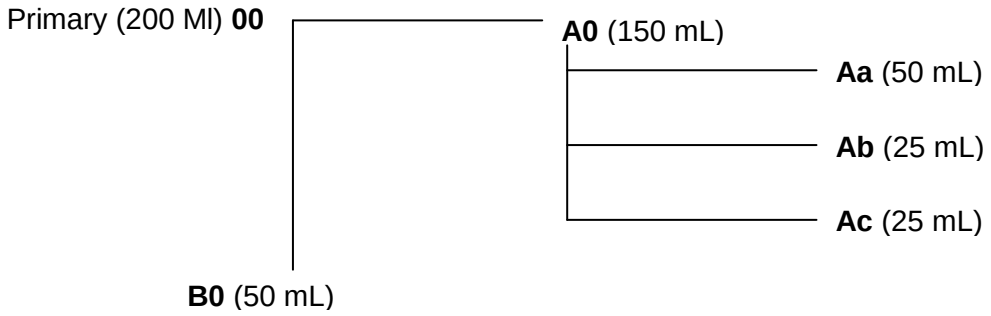
Examples of Use

As a specific example of this scheme in practice, consider a 300 Ml unit of AS-1 Red Blood Cells divided into two 150 Ml subunits (that are denoted by ds = A0 and ds = B0). One of these 150 Ml subunits (B0) is subsequently divided into one 100 Ml subunit (denoted by ds = Ba) and two 25 Ml subunits (denoted by ds = Bb and ds = Bc) for pediatric/neonatal use.



Note that although B0 was divided into subunits of different sizes, the nomenclature is independent of volume.

As another example, consider a 200 Ml unit of CPDA-1 Red Blood Cells divided into one 150 Ml subunit and one 50 Ml subunit (that are denoted by ds = A0 and ds = B0, respectively). The 150 Ml subunit (A0) is subsequently divided into one 50 Ml subunit (denoted by ds = Aa) and two 25 Ml subunits (denoted by ds = Ab and ds = Ac) for pediatric/neonatal use. Some blood (50 Ml) remains in the A0 division.



8.2 Data Structure 003 — Product Code: Division Code or Pack Number for Tissues

For tissue products, the use of tds, the last three characters of the Product Code (see 2.4.3, page 29) is different than it is with blood and cellular therapy products. First, there are three characters to denote divisions or packs, and second, there is no constraint that the products differentiated by tds be identical except for volume.

The division code or pack number is used to ensure traceability for each product having the same Donation Identification Number. It may be used in two different ways:

8.2.1 Each Product Given a Unique tds

In this situation, each tissue product that came from a single donation event is assigned a different tds value. This would usually be done sequentially, starting with 001 and going up to 999. This system becomes essential if the generic product description code (T0000) is used during implementation of ISBT 128.

T0001001 Frozen Femoral Head, Product 1
T0025002 Freeze Dried Ground Bone, Product 2
T0038003 Freeze Dried Strut, Narrow, Product 3

8.2.2 Multiple Identical Products Given a Unique tds

tds may also be used solely to differentiate identical products with the same DIN.

T0051001 Container 001 of Cleaned Frozen Cancellous Bone Chips|Pack|Irradiated
T0051002 Container 002 of Cleaned Frozen Cancellous Bone Chips|Pack|Irradiated
T0051003 Container 003 of Cleaned Frozen Cancellous Bone Chips|Pack|Irradiated

T0102001 Container 001 of Freeze Dried Skin, Small|ETO
T0102002 Container 002 of Freeze Dried Skin, Small|ETO

8.3 Data Structure 012—Special Testing: Red Blood Cell Antigens–General

The following is an example of the use of Data Structure 012 (Table 9).

Example 1:

Consider the following data content string:

8800000087000000

this data content string is decoded as follows:

C-c+E-e+, K+k+;
Cw, Mi^a, M, N, S, s, U, P1, Lu^a, Kp^a, Le^a, Le^b not tested;
Fy(a+b+), Jk(a+b-),
Do^a, Do^b, In^a, Co^b, Di^a, VS/V, Js^a, CMV antibody not tested.

Example 2:

6799999999999999

decodes as:

C+c-E-e+, K+k-, no other information.

Example 3:

9999999999999991

decodes as:

CMV antibody negative; no other information.

Example 4:

4868813558000000

decodes (rearranged to conform to a typical reporting practice) as:

C+C^w+c+E+e+ K+ k+ M+N+S+s+ P1- Lu(a-) Le(a-b+) Fy(a-b+) Jk(a+b+);
VS/V Mi^a U Kp^a Js^a Di^a Do^a Do^b Co^b In^a and CMV not tested.

The interpretation of the two (2)-character "ii" data content string is as follows. If the "ii" string is "99," then no information is provided (the default). If a number between "01" and "98" appears, the antigen (or characteristic) shown next to the value in Table 12, page 80, has been tested for and found negative (except for parvovirus). For example, "55" indicates Di(b-). If the value is "00," then further information is provided, either on the container label, or in some other manner.

National guidelines should be consulted for specific information regarding the printing of this bar code text. As a further example, rather than the complete red blood cell phenotype associated with Data Structure 012, the bar code text may read:

Phenotype provided in accompanying documentation

or some similar phrase. Alternatively, the antigen profile relevant to the recipient may be emphasized with the notation that the remainder of the interpretation of the bar code is presented elsewhere.

8.4 Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens

Examples of Use

Refer to Table 14, beginning on page 82; Table 15, page 84; and Table 16, page 85.

An individual of homozygous HLA-A2, B7 type and no information about platelet-specific antigens would be coded as:

029907999999999900 (if only the phenotype is known)
020207079999999900 (if the genotype is known)

Two AA values are always needed, followed by two BB values. To conform to practice the lower value should always be listed first.

An individual of HLA-A210, 24; B8, 2708 and no information about platelet-specific antigens would be coded as:

022408279999999900

An HPA-1a (PlA1)-negative individual when there is no HLA typing data would be coded as:

999999993999999900

An HPA-1a (PlA1)-negative individual of HLA phenotype A2, B8 would be coded as:

029908993999999900

An IgA-deficient, CMV-antibody negative individual would be coded as:

999999999999999400

8.5 Data Structures 015 and 016 — Special Testing: HLA-A, -B, and –DRB1 Alleles

Note: These data structures have been retired.

8.5.1 Tables for Data Coding

Refer to tables described in 3.2.1, page 91.

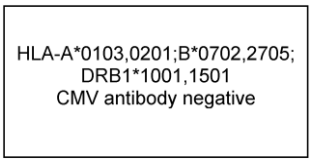
8.5.2 Examples of Use

Two HLA- A values (EEEE and FFFF) are always needed, followed by two HLA-B values (GGGG and HHHH) and two HLA-DRB1 values (IIII and JJJJ). To conform to practice the lower value of each pair should always be listed first.

A CMV antibody negative individual with the genomic typing HLA-A*0103, 02011; B*0702, 27052; DRB1*1001, 15011 would be coded as:

0103 0201 0702 2705 19
1001 1501 9999 9999 99

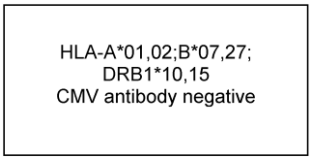
and the bar code text would appear as:



The same individual typed by low resolution genomic typing would be coded as:

0100 0200 0700 2700 19
1000 1500 9999 9999 99

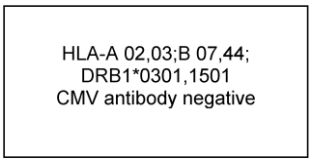
and the bar code text would appear as:



A CMV antibody negative individual with the serological HLA class I typing HLA-A2, 3; B7, 44 and the genomic typing HLA-DRB1*0301, 1501 would be coded as

0200 0300 0700 4400 19
0301 1501 9999 9999 99

and the bar code text would appear as:

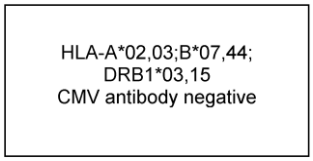


Note that because the HLA-A and –B typing is serological, there is no "" preceding the value in the bar code text.*

The same individual typed by low resolution genomic typing would be coded as:

0200 0300 0700 4400 19
0300 1500 9999 9999 99

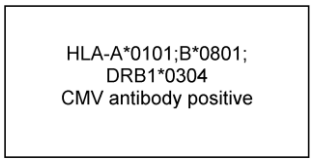
and the bar code text would appear as:



A CMV antibody positive HLA homozygous individual with the genomic typing HLA-A*0101; B*0801; DRB1*0304 (confirmed by family typings) would be coded as:

0101 0101 0801 0801 29
0304 0304 9999 9999 99

but the bar code text would appear as:

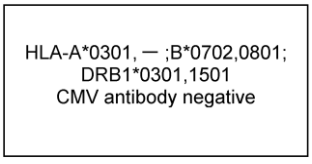


in accordance with current reporting convention.

Null alleles are coded according to the phenotype, i.e., a CMV antibody negative individual with the genomic typing HLA-A*0301, 2611N; B*07022, 0801; DRB1*03011, 1501 would be coded as:

0301 0000 0702 0801 19
0301 1501 9999 9999 99

and the bar code text would appear as:



8.6 Data Structure 023 Compound Messages

Compound messages allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems (see 2.4.23, page 54).

Examples:

A compound message using defined structured message 003 would look like:

=+04003=G15170612345600=%5100=<E0001000&>0060252359

where

=+04003 identifies this as a compound message of four data structures using the format defined for structured message type 003;

=G15170612345600 is the Donation Identification Number Data Structure;

=%5100 is the Blood Groups Data Structure;

=<E0001000 is the Product Code Data Structure;

&>0060252359 is the Expiration Date and Time Data Structure.

An undefined message example is:

=+03000=G15170612345600=%5100&(N0001

where

=+03000 identifies this as an undefined message structure containing three ISBT 128 data structures. The three following data structures have to be parsed and identified on the basis of their data identifiers.

In this case the three following data structures are Donation Identification Number [001], Blood Groups [002], and Special Testing: General [010].

8.7 Data Structure 027 Infectious Markers

The Infectious Markers Data Structure allows complex testing information to be conveyed electronically (see 2.4.27, page 59).

Example: A product has the following test results:

HIV-1/2 antibody	Negative
HIV-p24	Not tested
HIV genomic	Not tested
HCV antibody	Positive
HCV antigen	Not tested
HCV genomic	Negative
HBc antibody	Negative
HBs antigen	Negative
HBV genomic	Not tested
HTLV-I/II antibody	Negative
Syphilis antibody	Negative
CMV antibody	Positive
CMV genomic	Not tested
EBV genomic	Not tested
WNV genomic	Not tested
Parvo B19 antibody	Not tested
Parvo B19 genomic	Not tested
Chagas antibody	Not tested

Using the Infectious Markers Data Structure, this would be encoded according to Table 18, page 87, as:

321415000000000000

9 Bar Code Concatenation

This chapter provides the technical description of ISBT 128 concatenation for Code 128 symbols. It assumes an understanding of concatenation concepts and the basic differences between ISBT 128 concatenation and standard Code 128 concatenation. Additional background information can be obtained from the ICCBBA publications *Technical Note 2*, *Length of the Product Code Bar Code and Concatenation* and *Technical Bulletin 5, Bar Code Scanner ISBT 128 Concatenation*. These documents may be found on the ICCBBA Website.

9.1 Temporal/Spatial Constraints

Temporal and/or spatial constraints shall be met before a pair of codes can be concatenated. The detailed requirements are:

- the gap between last bar of the left bar code and the first bar of the right bar code shall be 36X ± 16X (That is equivalent to 9 ± 4 mm when the X dimension is 0.25 mm)
- both bar codes shall be oriented in the same manner (the Standard allows flexibility to accommodate slight misalignment, but labels should be affixed so that the bars in the bar codes are as close to parallel as possible)
- vertical alignment shall allow a single straight line scan to pass completely through both bar codes
- no vertical lines may appear between pairs of bar codes that are meant to be concatenated
- the stop codes shall be on the same side of both bar codes

Other variations of label design or placement shall not interfere with concatenation of paired bar codes (DIN and Blood Group; Product Code and Expiration Date and Time; and Container Manufacturer and Catalog Number and Container Lot Number).

In addition to these requirements, the X dimensions of both bar codes should be the same.

Note: The previous mandatory requirement for having the same X dimension for both bar codes was removed in version 3.0.0. However, recent evidence indicates this may cause problems. Until further evidence is available, we strongly recommend that the two bar codes be of the same X dimensions.

If any of the above constraints are not met the concatenation process shall be aborted. The scanner/decoder should immediately output the data of the correctly-read first bar code as if read without concatenation (this may be either bar code of the pair depending on the direction of scan). Reading and output of data from any other bar codes scanned then continues as an independent operation, as if a new scan had been started.

The techniques recommended to scanner manufacturers to ensure that the spatial separation constraint is applied are detailed in *Technical Bulletin 5*.

No maximum length for a pair of bar codes for concatenation is defined. However, the maximum length of a code pair that can be read will be determined by the scanner design.

9.2 Output Data String

ISBT 128 concatenation shall result in a single output data string containing the data from the left bar code followed by the data from the right bar code, regardless of the order of scanning. The terms left and right bar code are defined such that the stop code of the left bar code is adjacent to the start code of the right bar code.

The output data string shall contain all data characters in each bar code, including the data identifiers, in left-to-right byte order (i.e., starting with the left primary data identifier) regardless of the direction in which the bar codes are scanned. Internal Code 128 control characters, such as start, stop, and subset shift are non-data characters and thus do not appear in the output string.

9.3 Controlling the Concatenation Process

At any point in the bar code data entry process one of the following concatenation requirements shall apply:

a) concatenated read required;
b) concatenated read prohibited;
c) concatenated read permitted but not required.

Enforcement of these requirements may be carried out either by the host application software or by programming the scanner.

Where control is carried out by the application software, the scanner shall be configured to allow both single and ISBT 128 concatenated reads. The application software can then apply the required control (a, b, or c) for each scanning transaction.

Alternatively, scanners that support internal control of ISBT 128 concatenation mode may be programmed to allow ISBT 128 concatenation mode configuration, allowing the scanner to be set to operate according to a, b, or c above. Requirements a and b are referred to as static modes, and when configured to one of these the scanner will enforce the requirement every time an ISBT 128 bar code is scanned. If the scanner is configured to dynamic mode, c, then both single and concatenated reads are allowed.

9.4 Verification of Valid Concatenation

The above rules ensure that a concatenated read occurs only when required. This section is concerned with verifying the pair of bar codes once they have been received.

The ISBT 128 concatenation methodology allows the concatenation of any pair of ISBT 128 bar codes; however, in general, only a limited set of bar code pairs will be concatenated. Once again, control over this verification can be carried out either by the host application software or by the scanner software.

Using application software control, the application may be written to accept only the expected concatenated pair at each input event. The scanner in this situation shall be configured to pass through any pair of valid ISBT 128 bar codes.

Alternatively, the scanner may be configured to allow only specific pairs of bar codes to be accepted. Where such control is used it is essential that the scanner configuration permit the table of acceptable bar code pairs to be modified and extended. A Concatenation Programming Bar Code has been provided as an ISBT 128 data structure to support the management of acceptable pairs. Detailed consideration of this process is provided in *Technical Bulletin 5.*

9.5 Commonly Concatenated Bar Code Pairs

The following is a list of bar code pairs that are commonly concatenated. The list is not exhaustive and the Standard allows any pair of ISBT 128 codes to be concatenated. Reference to the corresponding data structure is given in parentheses.

- Donation Identification Number [001] and Blood Groups [ABO and RhD] [002]
- Product Code [003] and Expiration Date and Time [005]
- Donation Identification Number [001] and Product Code [003]
- Donation Identification Number [001] and Donor Identification Number [019]
- Container Manufacturer and Catalog Number [017] and Container Lot Number [018]
- Manufacturer and Catalog Number: Items Other Than Containers [021] and Lot Number: Items Other Than Containers [022]
- Patient Birth Date [024] and Patient Identification Number [025]

It is possible to concatenate other pairs of ISBT 128 bar codes and these can be specified within some scanner systems (see *Technical Bulletin 5*).

10 Blood Container Manufacturers Information Data File Specification

10.1 Introduction

The purpose of this data file is to provide a mechanism for electronically transferring information about blood container sets that will assist in process control. This data can be used to track and/or limit usage of the set; to verify that the product in the container is appropriate for the container; and to minimize the need for manual record keeping.

For the purposes of standardization, the data file structure, field definitions and formats, and default values are defined by ICCBBA.

Manufacturers are responsible for providing their own data files which are maintained in an electronic format available to their customers.

Data files are associated with a container set through the Container Manufacturer and Catalog Number [Data Structure 017] present on the base label of the container. The data file for each catalog number includes information that is:

Specific to the collection set:

- Number of containers in the set
- Intended use of each container (i.e., red cells, whole blood, plasma, platelets, or buffy coat)
- Nominal collection volume for the primary container (optional)
- Presence of fluids in containers that are not suitable for storage of blood or cellular therapy products (optional)

Specific to the container:

- Which container (red cell/whole blood, plasma, platelets, or buffy coat) within the set is being scanned
- Amount and type of fluid as supplied (anticoagulant, additive, etc.)
- Nominal, minimum, and/or maximum volume that each container is designed to hold (optional)
- Whether the container is downstream from a leukocyte reduction filter

Users may download into their information system the data file for each blood container catalog number purchased. With appropriate software, the catalog number bar code on a blood container can be scanned during use and linked to the data file to obtain or document a complete description of the set and containers. For example, by scanning the bar code on a whole blood collection set and linking it to the data file, the user can document the set manufacturer, the intended collection volume (e.g., 450 mL), the anticoagulant and its volume, and the number and type of attached containers.

The information in this data file is not intended as a specification of a container or a container set, but solely to provide process control information for use in blood collection management systems.

10.2 Structure of the Data File

The data file structure specifies the field definitions and formats together with default values and lookup table references. Beginning with Version 05 of the Manufacturers Data File, the message structure may be in either an XML message or an ASCII text file using comma separated values (CSV). A separate data file shall be created for each catalog number. The structure shall comprise a header line, a variable number of data lines, and for CSV files, a footer line.

Each data line shall be identified by a data label indicating what information the line contains. Data labels, together with the format of the data content, shall be assigned by ICCBBA to ensure commonality across all suppliers. The data line shall also contain a container identification character to indicate which container in the set is being described. The container identification character shall be set to the hash/number symbol (#) for information common to the entire set.

The data file specification shall be version controlled with the version number being held in the header line.

Table 37 Header Line [RT031]

Field	Length	Format	Comment
1	8	Alpha (8)	Fixed text “ICCBBAMF” identifies this as an ICCBBA-specified Manufacturers File format
2	2	Numeric (2)	Two (2)-digit version number identifies the version of the data structure with which this message is compliant (currently all messages are 05, i.e., this version of the data file)

Table 38 Data Lines [RT032]

Field	Length	Format	Comment
1	max 20	Alphanumeric (max 20)	ICCBBA-defined Data Label (see Table 40)
2	1	Alphanumeric or "#" (1)	Set to # for information relevant to the whole set, or the container identification character from the Container Manufacturer and Catalog Number Data Structure [017] for information specific to all containers with this identification character in the set. Numeric container identification characters shall be used for whole blood and other non-apheresis collection sets. 1 shall be reserved for the primary collection container. Alphabetic (A-Z) container identification characters shall be used for apheresis sets. Transfer sets shall use zero (0) for container identification. If multiple bag types are found in a transfer bag set, numeric characters 2-9 shall be used.
3	variable	Alphanumeric (var)	Data content (see below). Data shall not contain the comma character as this is the field delimiter. Other non-alphanumeric characters used as default delimiters in HL7 messages should also be avoided (|^~\&)

Table 39 Footer Line [RT033]

Field	Length	Format	Comment
1	8	Alpha (8)	Fixed text "FILETERM"
2	Variable	Numeric	Count of number of data lines in file

Table 40 ICCBBA-Assigned Data Labels and Content (Version 05) [RT034]

Data Label	Content	Format (max length)	Required *	Default Value	Application
MANUFACTURER	Identity of the container set manufacturer (uses the ICCBBA identification letters assigned in the Manufacturer Identifier Codes, see RT016)	Alpha (2)	M	N/A	Set
CATALOGNUMB	Manufacturer's catalog number (seven data characters as read from Container Manufacturer and Catalog Number Data Structure)	Alphanumeric (7)	M	N/A	Set
CATNUMBTEXT	Manufacturer's catalog number as printed in documentation	free format	M	N/A	Set
GS1GTIN	The GS1 Global Trade Item Number	Numeric (14)	O	N/A	Set
GS1GTINCONTENT	The number of items in the carton	Numeric (3)	O	N/A	Set
CONTAINERNUMB	Number of containers in set (when field 2 = #) or number of containers with specified container identification character (when field 2 = container identification character).	Numeric (2)	M	N/A	Set
COLLECTIONVOL	The nominal collection volume for whole blood donations (in Ml)	Numeric (3)	O	N/A	Set

Data Label	Content	Format (max length)	Required *	Default Value	Application
CONTENT	The fluid content of the container as supplied (anticoagulant, additive, etc.)	select from ICCBBA lookup table‡	D	NONE	Container
CONTENTVOL	The volume of the fluid described in the CONTENT field (in Ml)	Numeric (3)	O	N/A	Container
PLTCONTAINER	Indicator if this is a container suitable for the storage of platelets (liquid phase)	Y or N	D†	N	Container
PMACONTAINER	Indicator if this is a container suitable for the storage of plasma (liquid or frozen)	Y or N	D†	N	Container
RBCCONTAINER	Indicator if this is a container suitable for the storage of red cells (liquid phase)	Y or N	D†	N	Container
BFYCONTAINER	Indicator if this is a container suitable for the storage of buffy coat (liquid phase)	Y or N	D†	N	Container
LEUKREDFILTER	Indicates whether the container is downstream of a leukocyte reduction filter	Y or N	D†	N	Container
NOMINALVOLUME	The volume of final product that the container is designed to hold (in Ml)	Numeric (4)	O	N/A	Container
MINVOL	The minimum amount of product that the container is designed to hold (in Ml)	Numeric (4)	O	N/A	Container
MAXVOL	The maximum amount of liquid	Numeric (4)	O	N/A	Container

Data Label	Content	Format (max length)	Required *	Default Value	Application
	product the container is designed to hold (in Ml)				
MAXFRZVOL	The maximum amount of frozen product the container is designed to hold (in Ml)	Numeric (4)	O	N/A	Container
SOLN1	A solution (e.g., additive solution or pathogen inactivation solution) that is integrally attached to the set but not contained within a container designed to store blood components	Alphanumeric (7)	O	N/A	Set
SOLN1VOL	The volume (in Ml) of Solution 1	Numeric (4)	O	N/A	Set
COMMENT	Field that is available for manufacturers to add comments; end-users are not expected to upload this information	Alpha (200)	O	N/A	Both

N/A = not applicable*; Y = yes; N = no
M = mandatory; O = optional (included at manufacturer's discretion); D = default value applies if the data line is not present
† At least one of the PLTCONTAINER, PMACONTAINER, RBCCONTAINER or BFYCONTAINER fields shall be set to Y for each container type
‡ This table can be found in the definitions for Core Conditions in the ICCBBA document *ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* in the Technical Documentation area of the ICCBBA Website.

10.3 Container Identification Character

The container identification character used on blood containers can be implemented in two distinct ways. The option adopted by any particular manufacturer will depend upon their manufacturing process. It would not be appropriate for a customer to place a requirement on a manufacturer to adopt either of these options. The structure of the data file has been configured to accommodate both options and software systems should to be designed to accept both.

Option 1
Each container in the set bears a unique container identification character. This is the simplest format, and each container will have a set of entries in the data file corresponding to its container identification character.

Option 2
Each distinct container in a set bears a unique container identification character. Where a set contains two or more containers that are identical in terms of their composition, purpose, and position in the configuration, then these containers may be given the same container identification character. In this case, the data field for the number of containers will indicate how many containers there are with the specified container identification character and there will be a single set of entries in the data file common to all these containers.

10.4 Further Guidance

Detailed information about implantation of the Manufacturers Data File, multiple examples of use, and example data files may be found in *Implementation Guide: Use of the Manufacturers Data File.* This document may be found on the ICCBBA Website.

11 Use of ISBT 128 Data Structures in HL7 Messages

Per its Website (www.hl7.org), Health Level Seven International (HL7) is "a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare."

HL7 is an electronic messaging standard that allows communication between disparate computer systems. Within an HL7 message, there may be coded values. Some of these coded values are from HL7 maintained tables, some are from user defined tables, and others are from external tables. According to the HL7 standard, an external table is "a set of coded values defined and published by another standards organization." ICCBBA is recognized by HL7 as such a standards organization. ICCBBA maintains tables, such as Table 41 [RT042], which is referenced in HL7 in its Vocabulary Table 0396 on the HL7 Website. This allows ICCBBA to specify how ISBT 128 data structures and other transfusion and transplantation information can be included in HL7 messages in a structured manner.

Table 41 [RT042] specifies identifiers that may be used in encoding ISBT 128 data structures into HL7 messages.

Table 41 IBT0001 Coding System Reference Table [RT042]

Identifier	Text Name	Description	Data example
IBT1-0001	Donation Number	Thirteen character donation number element from an ISBT 128 Donation Identification Number [Data Structure 001]. (In this case includes the second data identifier which is also the first data character)	G151708123456
IBT1-0002	Flag Value	Two character code corresponding to the flag characters from an ISBT 128 Donation Identification Number [Data Structure 001]. See Table 4 for acceptable values and their interpretation.	01
IBT1-0003	Donation and Flag	Fifteen-character code corresponding to an ISBT 128 Donation Identification Number [Data Structure 001] (In this case includes the second data identifier which is also the first data character). See Table 3 [RT004] for acceptable values of flag element and their interpretation.	G15170812345601

Identifier	Text Name	Description	Data example
IBT1-0004	Blood Groups	Four character code corresponding to an ISBT 128 Blood Group [ABO and RhD] [Data Structure 002]. See Table 4 [RT005] and Table 5 [RT006] for acceptable values and their interpretation.	5100
IBT1-0005	ABO RhD	ISBT 128 two character ABO/RhD code. See Table 4 [RT005] for acceptable values and their interpretation.	51
IBT1-0006	Special Messages	ISBT 128 two-character Special Message. See Table 5 [RT006] for acceptable values and their interpretation.	Mq
IBT1-0007	Rh K Mur	ISBT 128 single character value corresponding to third data character of Data Structure 002 and encoding Rh, Kell and Mi^{a}/Mur phenotypes. See TS Table 6 [RT007] for acceptable values and their interpretation.	B
IBT1-0008	Product Code	Eight character ISBT 128 Product Code [Data Structure 003], ISBT 128 Product Database and Table 7 [RT008].	E0001V00
IBT1-0009	Product Type	Five character code corresponding to the first five characters of an ISBT 128 Product Code [Data Structure 003] and referencing a value in the ISBT 128 Product Database.	E0123
IBT1-0010	Type of Donation	Single character code corresponding to the sixth character of an ISBT 128 Product Code [Data Structure 003] and specifying donation type. See Table 7 [RT008] for acceptable values and their interpretation. Not used for tissue products.	V
IBT1-0011	First Division	Single character code corresponding to the seventh character of an ISBT 128 Product Code [Data Structure 003] and indicating first division value. Not used for tissue products.	A
IBT1-0012	Second Division	Single character code corresponding to the eighth character of an ISBT 128 Product Code [Data Structure 003]. Not used for tissue products	b

Identifier	Text Name	Description	Data example
IBT1-0013	Division Number	Three digit code corresponding to the sixth to eighth character of an ISBT 128 Product Code [Data Structure 003] for use with tissue products only and indicating the division number of the product.	017
IBT1-0014	Expiration Date	Six digit code corresponding to an expiration date as defined for ISBT 128 Data Structures 004 and 005.	008120
IBT1-0015	Expiration Time	Four digit code corresponding to an expiration time as defined for ISBT 128 Data Structure 005.	1900
IBT1-0016	Collection Date	Six digit code corresponding to a collection date as defined for ISBT 128 Data Structures 006 and 007.	008120
IBT1-0017	Collection Time	Four digit code corresponding to a collection time as defined for ISBT 128 Data Structure 007.	1900
IBT1-0018	Production Date	Six digit code corresponding to a production date as defined for ISBT 128 Data Structures 008 and 009.	008120
IBT1-0019	Production Time	Four digit code corresponding to a production time as defined for ISBT 128 Data Structure 009.	1900
IBT1-0020	Special Testing General	Five character code corresponding to an ISBT 128 Special Testing – General code [Data Structure 010]. See Special Testing: General Database Table for acceptable values and their interpretation.	N0001
IBT1-0021	Special Testing RBC General	Eighteen digit code corresponding to an ISBT 128 Special Testing: Red Blood Cell Antigens – General code [Data Structure 012]. See Table 9 [RT009] and Table 12 [RT011] for acceptable values and their interpretation.	486881355800000000
IBT1-0022	Special Testing RBC Finnish	Eighteen digit code corresponding to an ISBT 128 Special Testing: Red Blood Cell Antigens – Finnish code [Data Structure 013]. See Table 10 [RT010] and Table 13 [RT012] for acceptable values and their interpretation.	486881355800000000

Identifier	Text Name	Description	Data example
IBT1-0023	Special Testing Platelets	Eighteen digit code corresponding to an ISBT 128 Special Testing: Platelet HLA and Platelet Specific Antigens code [Data Structure 014]. See Table 14 [RT013] and Table 15 [RT014] for acceptable values and their interpretation.	022408279999999900
IBT1-0024	Special Testing HLA	Eighteen digit code corresponding to an ISBT 128 Special Testing: HLA-A and –B Alleles code [Data Structure 015]. See the IMTG/HLA database (http://www.ebi.ac.uk/imgt/hla/) and [RT015] for acceptable values and their interpretation.	010302010702270519
IBT1-0025	Special Testing DRB1	Eighteen digit code corresponding to an ISBT 128 Special Testing: HLA-DRB1 Alleles code [Data Structure 016]. See the IMTG/HLA database (http://www.ebi.ac.uk/imgt/hla/) for acceptable values.	100115019999999999
IBT1-0026	Container Mfr and Cat	Ten character code corresponding to an ISBT 128 Container Manufacturer and Catalog Number [Data Structure 017]. Refer to [RT016] for manufacturer codes.	1BA0027QZE
IBT1-0027	Container Lot	Ten character code corresponding to an ISBT 128 Container Lot Number [Data Structure 018].	0000123456
IBT1-0028	Donor ID	Twenty-one character code corresponding to an ISBT 128 Donor Identification Number [Data Structure 019].	W00000000000012436744
IBT1-0029	Staff ID	Eleven character code corresponding to an ISBT 128 Staff Member Identification Number [Data Structure 020].	W0000016902
IBT1-0030	Other Mfr and Cat	Ten character code corresponding to an ISBT 128 Manufacturer and Catalog Number: Items other than containers [Data Structure 021]. Refer to [RT016] for manufacturer codes.	IS000RA123
IBT1-0031	Other Lot	Ten character code corresponding to an ISBT 128 Lot Number: Items Other Than Containers [Data Structure 022].	0000435678

Identifier	Text Name	Description	Data example
IBT1-0032	Patient DOB	Ten character code corresponding to an ISBT 128 Patient Date of Birth [Data Structure 024]. Note that this structure includes a location code (defined on RT018) together with the Date of Birth in yyyymmdd format	0119541217
IBT1-0033	Patient ID	Variable length field corresponding to an ISBT 128 Patient Identification Number [Data Structure 025]. Note that this structure includes a location code (defined on RT018) and patient number field length together with the patient number	0106923832
IBT1-0034	Infectious Markers	Eighteen digit code corresponding to an ISBT 128 Infectious Markers code [Data Structure 027]. See [RT019] for acceptable values and their interpretation.	321415000000000000
IBT1-0035	Dimensions	Variable length field corresponding to an ISBT 128 Dimensions [Data Structure 029]. Refer to Table 19 [RT0037], Table 20 [RT038], and Table 21 [RT039]	01010007000310 00
IBT1-0036	Red Cell Antigens with Test History	Variable length field corresponding to an ISBT 128 an ISBT 128 Red Cell Antigens with Test History [Data Structure 030]. Refer to Table 22 [RT040] and Table 23 [RT041].	0040040020201004004020400400301030040050202

12 ICCBBA

12.1 Formation and Incorporation

ICCBBA was established in 1994 to support ISBT 128 and to assist in its implementation. ICCBBA was incorporated in the Commonwealth of Virginia in 1995, and is a 501(c)(3) not-for-profit organization.

12.2 Registration and Licensing

Each facility that implements ISBT 128, or plans to implement ISBT 128 and needs access to password-protected information from the ICCBBA Website, must register with ICCBBA. Specific requirements for registration and a form for this purpose may be found on the ICCBBA Website. Special arrangements are available for facilities in developing countries that wish to use ISBT 128 Donation Identification Numbers in an eye-readable format only.

Before implementing ISBT 128, each registered facility shall pay the annual license fee. The annual license fee is set by the ICCBBA Board of Directors to cover the anticipated expenses for the fiscal year for which the fee is assessed. It is invoiced to every registered facility at its last known address early in each calendar year. Failure to pay the annual fee is an indication that the facility will no longer be using or providing support for ISBT 128. The terms under which ISBT 128 is licensed for use are provided in the ICCBBA License Agreement, a copy of which can be found on the ICCBBA Website.

ICCBBA assigns facility and manufacturers codes. The facility codes are published in the password-protected area of the ICCBBA Website.

Vendor codes for manufacturers who encode their identities in Data Structure 017 or 021 are found on Table W1 [RT016] on the ICCBBA Website. Vendors may obtain codes by contact the ICCBBA office.

12.3 Code Assignment

All codes used in ICCBBA data structures, with the exception of those codes designed specifically for national or local use, are assigned by ICCBBA. Once assigned, the codes are kept in the appropriate reference table or database table. Reference tables and database tables are found either in this document or in the password-protected area of the ICCBBA Website.

12.4 Issuing Agency Identifier

ICCBBA has been recognized as an Issuing Agency of unique identifiers under ISO/IEC 15459. This standard specifies procedural requirements to maintain a non-significant, unique identifier for item management applications and outlines the obligations of the Registration Authority and Issuing Agencies.

The ICCBBA Issuing Agency Code (IAC) is **LI**.

Acronyms

ANSI American National Standards Institute

ASCII American Standard Code for Information Interchange

DIN Donation Identification Number

EBMT European Group for Blood and Marrow Transplantation

EDI Electronic Data Interchange

FACT Foundation for the Accreditation of Cellular Therapy

FIN Facility Identification Number

HLA Human Leukocyte Antigen

HL7 Health Level 7

IEC International Electrotechnical Commission

IMGT International ImMunoGeneTics project

ISCT International Society of Cellular Therapy

ISO International Organization for Standardization

JACIE Joint Accreditation Committee of ISCT and EBMT

RFID Radio Frequency Identification

WHO World Health Organization

Glossary

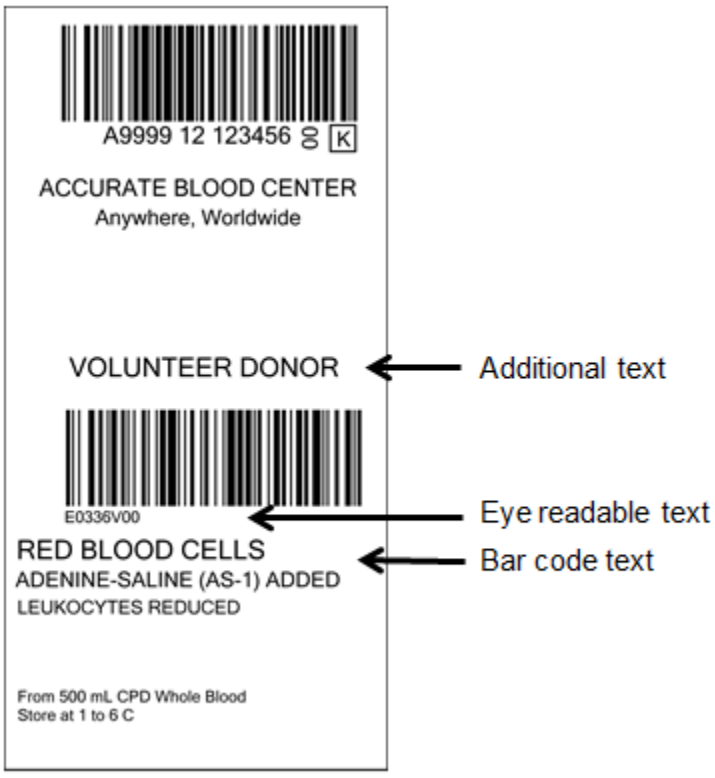
Bar code	A symbolic representation of a data structure that also includes the symbology-specific start and stop codes.	
	Linear bar code	Single row of bars and spaces In this document the unqualified use of linear bar code implies the use of Code 128 symbology with its associated modulo 103 check character.
	2-D bar code	Two-dimensional pattern of data cells In this document the unqualified use of 2D bar code implies the use of Data Matrix
Check character	A character used to ensure the accuracy of data. The value is calculated based on an algorithm applied to the data. Examples are the modulo 103 check character internal to Code 128 and the ISO/IEC 7064 modulo 37-2 check character appended to eye-readable text that verifies accurate keyboard entry.	
Concatenation	A method by which the information held in two bar codes is combined in the scanner into a single string of data before being sent to the host computer. ISBT 128 places specific rules on the operation of concatenation which ensures that the two codes are adjacent to one another, hence allowing this feature to be used in label process control. (Note: ISBT 128 concatenation is a specific enhancement to the Code 128 Specification. See Chapter 9 for more information.)	
Container set	Any combination of containers, tubing, and other items as packaged by the manufacturer, intended for the collection of whole blood, apheresis, or cellular therapy procedures.	
Control character	A character inserted into a bar code to control the decoding process (such as that used to indicate a change in the Code 128 symbology subset). In most circumstances these are stripped by the scanner and not transmitted to the host.	
Data character	The individual ASCII characters that make up the data content.	
Data content	The characters in a data structure that encode the information for which the data structure is named. The data content does not include the data identifier. (The Donation Identification Number is an exception to this rule. See Section 2.4.1, page 24.)	

Data identifier	The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. (The Donation Identification Number is an exception to this rule. The second character of the data identifier can never be dropped because it is also part of the data content. See 2.4.1, page 24.)	
Data structure	Information content comprising the data identifier and data content. When a data structure is represented as a bar code, the term data structure does not include the symbology-specific and always present start and stop codes, the modulo 103 check character, or any specified control characters.	
Donation Type	A designation indicating why a donation was collected	
	Autologous donation	A donation collected from a donor for his or her own use.
	Dedicated donation	A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).
	Designated donation	A collection from a donor called by the collecting facility to provide product (for example, HLA-compatible) to be used by a specific recipient (or for Cellular Therapy products, possibly a small group of recipients).
	Directed donation	A collection from a donor who presents to the collecting facility at the request of another person intending to provide product to be used by that person.
Facility	An organization that is responsible for the collection/recovery, processing, and/or distribution of ISBT 128-encoded products.	
Flag character	Part of the data content of a data structure used in process control or data transmission checking. Printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.	
ISBT 128	An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.	
Julian Date	See Ordinal Date.	
Label	An independent entity that may carry one or more bar codes and also provides eye-readable information about the product.	
	Affixed label	A label that adheres in physical contact with the product container.

	Attached label	A label that is fastened securely to the product container by means of a tie tag or comparable alternative.
	Accompanying documentation	Documentation containing product information that is together with the product, or is available to the appropriate individual(s) electronically, but is not affixed or attached to the product.
	Base label	The label placed on a container by a manufacturer. It carries the manufacturer's identity, the catalog number of the container (or container set), and the lot number of the container (or container set) encoded as ISBT 128 data structures.
	Final label	Labeling as it appears on a product ready for release to another entity or for administration to a recipient.
	Partial label	A label that because of size or other constraints does not contain all the required information.
Ordinal Date	A system for maintaining dates that numbers the first day of the year (January 1) as 1 and the last (December 31) as 365 or 366 (in a leap year). Also known as Julian Date.	
Plasma Derivative	A product that contains concentrated fractions of plasma proteins that have been separated using physico-chemical or other fractionation processes. It is made from pooling plasma from large numbers of donors and is traced based on the lot or batch number of the pooled product.	
Primary container	The container into which the whole blood is drawn.	
Retired	A mechanism utilized by ICCBBA to phase out a data structure or code that has become outdated, inadequate, inappropriate, redundant, or discovered to be in error. Because data structures or codes may exist on the labels of products in inventories across the world, the data structures and codes must be retained in the database for backward compatibility. The date on which a data structure or code is retired will be noted in the document in which it appears. This date indicates the date on which ICCBBA recommended the data structure or code no longer be used for new products. Software should be written to recognize these codes, but not assign them to newly created products. It is understood that facilities need time to retire codes after ICCBBA has made its recommendation.	
Satellite container	A container other than the primary container in a container set.	
Text	(See Figure 10, page 146)	

	Eye-readable text	The eye-readable representation of the data characters in a bar code (printed left justified immediately below the bar code, unless otherwise specified).
	Bar code text	The interpretation of the eye-readable text (the data content of the bar code).
	Additional label text	All other information on the label that is not associated with a bar code.
Transfer container	A container intended for post-manufacturing connection to a container set.	
UTC	Universal Coordinated Time, similar to GMT (Greenwich Mean Time), marks the starting point of every time zone in the World. UTC does not change based on daylight saving (summer) time; thus, the relationship of local time to UTC changes if daylight saving (summer) time is observed.	

Figure 10 Illustration of the Terms Eye-Readable Text, Bar Code Text, and Additional Label Text



Appendix A Donation Identification Number Check Character [K]

A.1 Keyboard Entry Check Character

ISBT 128 Donation Identification Numbers utilize checksum characters based on the ISO 7064 Mod 37-2 algorithm. This Appendix shows how to calculate the checksum character for any given Donation Identification Number. The calculation is based on the DIN thirteen (13)-character string (*i.e.*, excluding the leading **=** symbol and the flag characters).

The steps in the process are as follows:

1. For each character in the string determine its check value as required by ISO 7064 from Table 42;
2. For each character in the string determine its weighted check value by multiplying the check value from Table 42 by the nth power of 2 where n is the position of the character from the right hand end of the string;
3. Sum the weighted check values from step 2;
4. Find the modulus 37 value of the sum from step 3 (the value **remaining** when the weighted sum is divided by 37);
5. Subtract the value obtained in step 4 from 38;
6. Find the modulus 37 value of the result of step 5 (the value **remaining** when divided by 37);
7. Using the value in Step 6, determine the check character by again referring to Table 42 (this time read the character from the value) — this is the modulo 37-2 checksum character (referred to as K throughout this *Standard*).

Table 42 Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character [RT035]

Character	0	1	2	3	4	5	6	7	8	9	A	B	C
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	E	F	G	H	I	J	K	L	M	N	O	P
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	S	T	U	V	W	X	Y	Z	*		
Value	26	27	28	29	30	31	32	33	34	35	36		

Example of Calculation

Donation number G1234 12 654321

Position from right (n)	2^n (a)	Character	ISO 7064 value (step 1) (b)	Weighted value (step 2) (a x b)
13	8192	G	16	131072
12	4096	1	1	4096
11	2048	2	2	4096
10	1024	3	3	3072
9	512	4	4	2048
8	256	1	1	256
7	128	2	2	256
6	64	6	6	384
5	32	5	5	160
4	16	4	4	64
3	8	3	3	24
2	4	2	2	8
1	2	1	1	2
Step 3	sum of weighted values			145538
Step 4	modulo 37 (first MOD)			17
Step 5	subtract from 38			21
Step 6	modulo 37 (second MOD)			21
ISO/IEC 37-2 checksum				21
ISBT 128 check character (K)				L

A.2 Computer Programs for Calculating K Using ISO 7064

This is an *informative* section designed to assist programmers by giving two representative methods for the calculation of the Donation Identification Number ISO 7064 modulo 37-2 check character. Both use the "*Pure system recursive method*" for calculation of the check character as documented in Section 7.1 of the ISO/IEC 7064 specification: "Information technology—Security techniques—Check character systems."

Programmers must validate that their programs and algorithms comply with the *normative* ISO/IEC 7064 2003 specification and good programming practice. Programs to generate the check character should also contain sufficient error checking to verify that the first character of the input Donation Identification Number is either an uppercase A–Z, or a digit 1–9 and that all subsequent characters in the input Donation Identification Number are digits.

The following PASCAL language function **ISOmod37_2** calculates and/or validates the ISO 7064 Mod 37-2 pure check character:

```
function ISOmod37_2(DonationInfo:string; K:integer) : char;
(Calculate or validate ISO mode 37-2 pure check character}
function ISOvalue(InputString:string; I:integer) : integer;
begin {Convert ASCII character value to ISO 7064 value in range 0...36}
case InputString[I] of
'0' .. '9': ISOValue := (ord(InputString[I]) - 48);
'A' .. 'Z': ISOValue := (ord(InputString[I]) - 55);
'*': ISOValue := 36;
end;
end {function ISOvalue};
var
J,Sum,CharValue,CheckValue : integer;
const
ISOCharTable : string[37] = '0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*';
begin
Sum := 0;
for J:= 1 to K do
begin
CharValue := ISOvalue(DonationInfo,J);
Sum := ((Sum + CharValue)*2) mod 37;
end;
{Check character value is defined to be congruent to 1 mod 37}
CheckValue := (38 - Sum) mod 37;
ISOmod37_2 := ISOCharTable[CheckValue + 1];
end {function ISOmod 37_2};
```


The following 'C' language function **CalculateMod37_2** also implements the *"Pure system recursive method*" documented in Section 7.1 of the ISO/IEC 7064: specification:

```
int CalculateISO7064Mod37_2(char *inputString)
{
int ch, sum, charValue, isDigit, isUpperAlpha;
static char iso7064ValueToCharTable[] =
"0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*";
// Read the characters from left to right.
for (sum = 0; ch = *inputString; inputString++)
{
// Ignore invalid characters as per ISO 7064.
isDigit = ((ch >= '0') && (ch <= '9'));
isUpperAlpha = ((ch >= 'A') && (ch <= 'Z'));
if (isDigit || isUpperAlpha)
{
// Convert the character to its ISO 7064 value.
if (isDigit)
charValue = ch - '0';
else
charValue = ch - 'A' + 10;
// Add the character value to the accumulating sum,
// multiply by two, and do an intermediate modulus to
// prevent integer overflow.
sum = ((sum + charValue) * 2) % 37;
}
}
// Find the value, that when added to the result of the above
// calculation, would result in a number who's modulus 37
// result is equal to 1.
charValue = (38 - sum) % 37;
// Convert the value to a character and return it.
return (iso7064ValueToCharTable[charValue]);
}
```

ICCBBA thanks Dr Clive Hohberger, Vice President of Technology Development at Zebra Technologies Corporation, Vernon Hills, Illinois, USA, for providing the PASCAL function ISOmod37_2, and Mr. Harold Boe, Vice President of Software Development at Seagull Scientific Systems, Inc, Bellevue, Washington, USA, for providing the C-language function CalculateISO7064Mod37_2.

Appendix B ISBT 128 Standard: Numbering of Versions of Documents and Databases

A three (3)-digit system shall be employed to distinguish versions of the ISBT 128 Standard documents and databases.

For documents:
ISBT 128 Standard documents shall include a version control sheet

- the third digit shall be increased by one whenever minor typographical errors are corrected or when language is clarified;
- the second digit shall be increased by one and the third digit returns to 0 whenever discreet new entries are made (e.g., a new data structure is inserted) or typographical errors with operational significance are corrected;
- the first digit shall indicate a major revision of the document.

For databases:
Databases shall have a version control sheet that shall be maintained on the ICCBBA Website.

For product description code database:
- the third digit shall be increased by one if the only change to the database is an addition to the Product Description table or minor corrections (e.g., spelling) in existing codes;
- the second digit shall be increased by one and the third digit returns to 0 if changes are made to the Class or Attribute tables;
- the first digit shall tie the database to the controlling major revision of the *ISBT 128 Standard Technical Specification*.

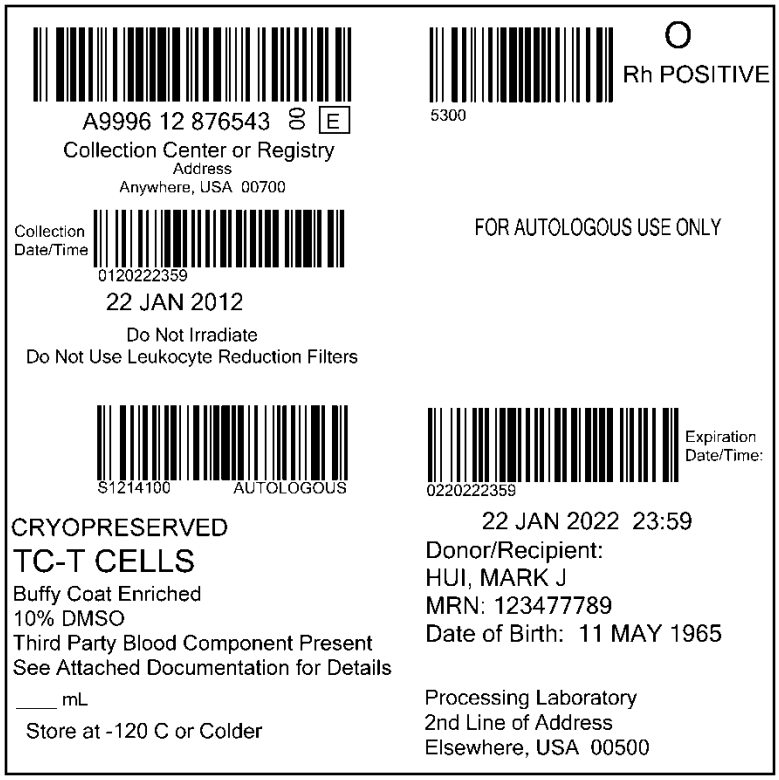
For Special Testing database:
- the third digit shall be increased by one if a typographical error is corrected;
- the second digit shall be increased by one and the third returns to 0 each time new item is added;
- the first digit shall tie the database to the controlling major revision of the *ISBT 128 Standard Technical Specification*.

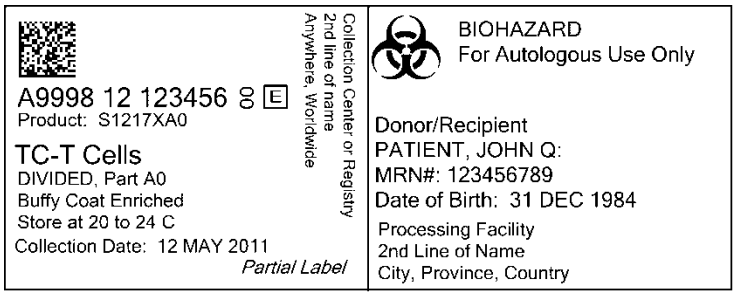
Appendix C Label Examples

Note: A library of example labels from different countries is posted on the ICCBBA Website. Additional label examples may be found in ISBT 128 Standard, Product Code Structure and Labeling documents (Cellular Therapy, and Blood Components).

Examples of tissue labels are included in the document ISBT 128 Standard Labeling of Human Tissue.

Figure 11 Cellular Therapy Example Labels





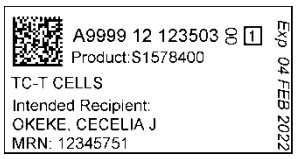
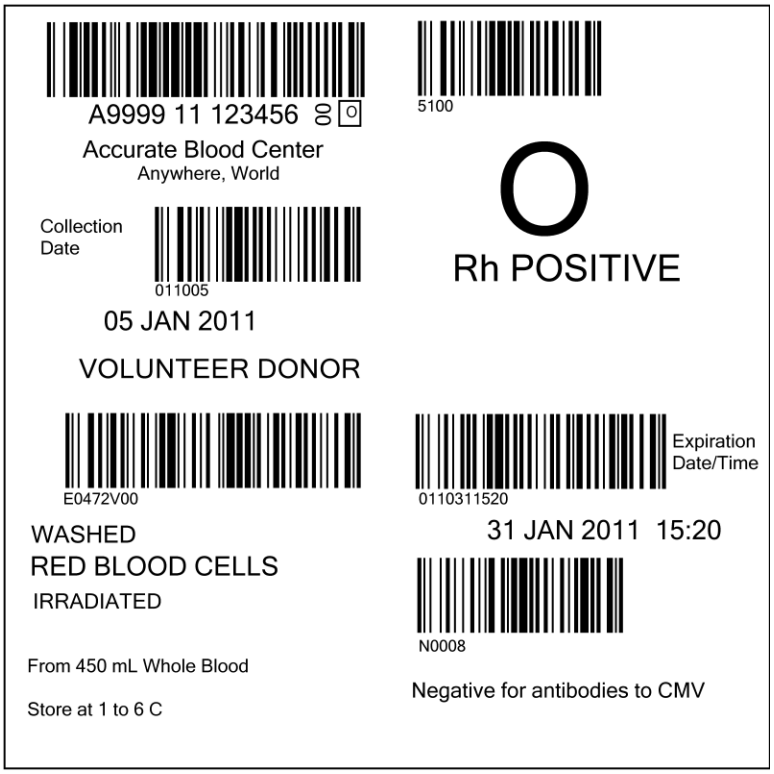


Figure 12 Blood Product Example Labels



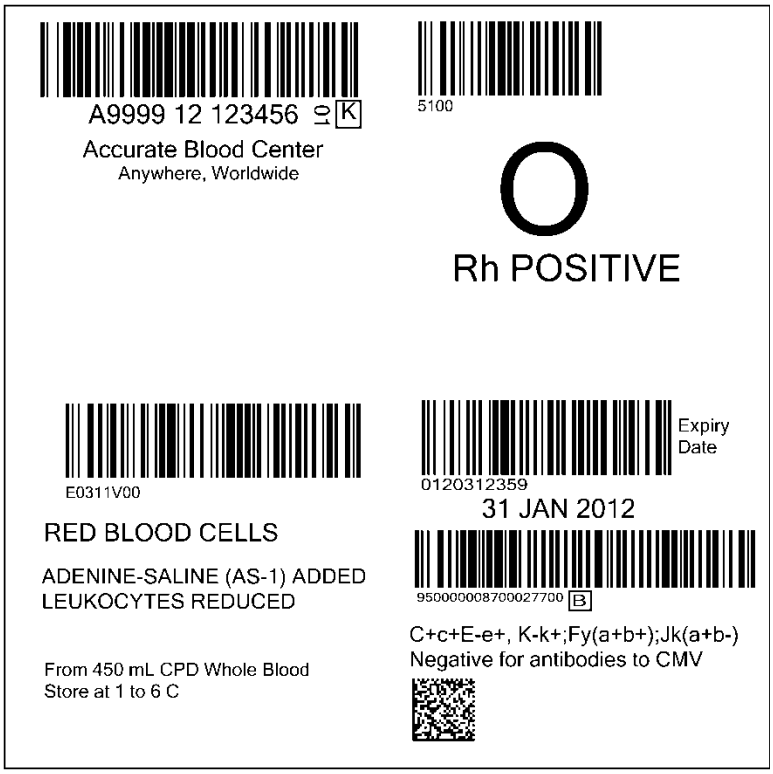
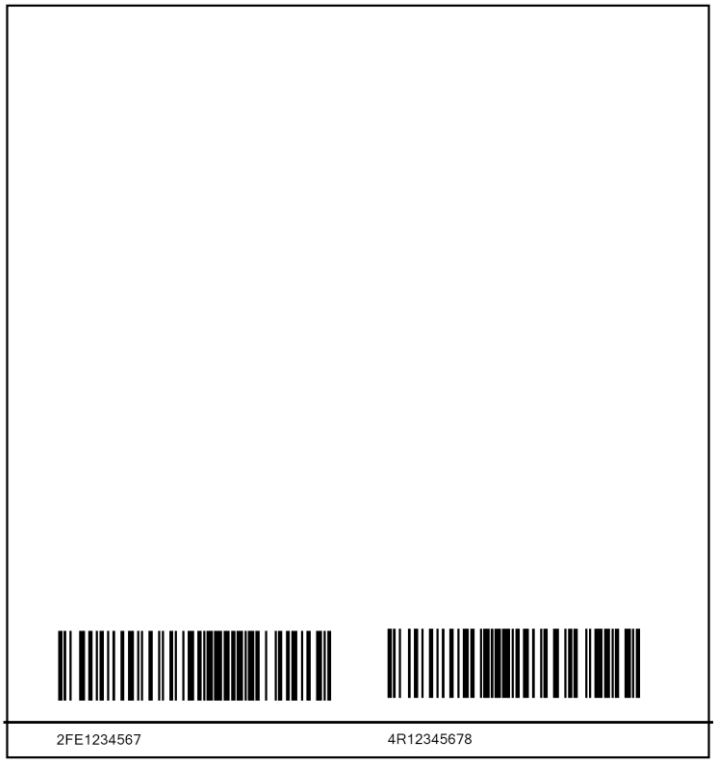


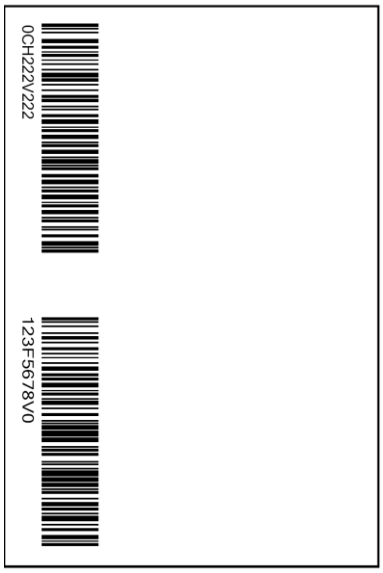
Figure 13 Example Base Label



This example represents the minimum amount of ISBT 128 information that shall appear on the label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

Figure 14 Example Small Base Label



This example represents the minimum amount of ISBT 128 information that shall appear on the label. Manufacturers may include additional information such as:

- icons
- user friendly catalog numbers and lot numbers
- the intended use of the bag in text (e.g., For Platelet Storage)
- appropriate warnings (e.g., Not Suitable for Storage of Red Blood Cells or the number of days a platelet product can be stored within the container)

Appendix D Cross-Reference for Table Numbers

Table 43 Cross-Reference for Table Numbers [RT036]

Reference Table Number	**Table Number in ISBT 128 *Standard Technical Specification* or Website reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification*** **(URL if the table is not found in the *ISBT* 128 *Standard Technical Specification)***
RT001	Table 1	Code 128 Subset B Characters Available for Use as ISBT 128 Data Identifiers [RT001]
RT002	Table 36	Table 36 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002]
RT003	Table 2	Index of Data Structures [RT003]
RT004	Table 3	Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]
RT005	Table 4	Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Donation or Collection Information [RT005]
RT006	Table 5	Data Structure 002: Special Messages [RT006]
RT007	Table 6	Data Structure 002: Rh, Kell, and Mia/Mur Phenotypes [RT007]
RT008	Table 7	Data Structure 003: Type of Donation or Collection in 6th Position of Product Code [RT008]
RT009	Table 9	Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 1 Through 9 [RT009]
RT010	Table 10	Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 1 Through 9 [RT010]
RT011	Table 12	Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT011]
RT012	Table 13	Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT012]
RT013	Table 14	Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 Through 8 [RT013]

Reference Table Number	Table Number in ISBT 128 *Standard Technical Specification* or Website reference	Name of Table in the *ISBT* 128 *Standard Technical Specification* (URL if the table is not found in the *ISBT* 128 *Standard Technical Specification)*
RT014	Table 15	Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 9 Through 16 [RT014]
RT015 (Retired)	Table 16	Data Structure 015: Special Testing: HLA-A and –B Alleles, Position 17 (CMV Antibody Status) [RT015]
RT016	ICCBBA Website	Data Structures 0017 and 021 W1 Manufacturer ID Codes (http://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables)
RT017	ICCBBA Website	Data Structure 023: W2 Structured Compound Messages (http://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables)
RT018	Table 17	Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number [RT018]
RT019	Table 18	Data Structure 027: Infectious Markers: Positions 1 through 9 [RT019]
RT020	Table 31	Positioning Bar Codes on the Base Labels [RT020]
RT021	Table 32	Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]
RT022	Table 33	Final Label Quadrants and Bar Codes [RT022]
RT023	Table 34	Required Positioning of Bar Codes on Final Labels [RT023]
RT024	Table 35	Recommended Positioning of Bar Codes on Final Labels [RT024]
RT025	Table 24	CLASS Table [RT025]
RT026	Table 25	ATTRIBUTE Table [RT026]
RT027	Table 26	PRODUCT DESCRIPTION Table [RT027]
RT028	Table 27	VERSION Table (Product Description) [RT028] (Product Description)
RT029	Table 28	Special Testing: General [RT029]
RT030	Table 30	Registered Facilities [RT030]
RT031	Table 37	Header Line [RT031]

Reference Table Number	**Table Number in ISBT 128 *Standard Technical Specification* or Website reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification*** **(URL if the table is not found in the *ISBT* 128 *Standard Technical Specification)***
RT032	Table 38	Data Lines [RT032]
RT033	Table 39	Footer Line [RT033]
RT034	Table 40	ICCBBA-Assigned Data Labels and Content (Version 05) [RT034]
RT035	Table 42	Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character [RT035]
RT036	Table 43	Cross-Reference for Table Numbers [RT036]
RT037	Table 19	Data Structure 029: Symbols [RT037]
RT038	Table 20	Data Structure 029: Dimensions [RT038]
RT039	Table 21	Data Structure 029: Decimal Point [RT039]
RT040	Table 22	Data Structure 030: RBC Serological Results [RT040]
RT041	Table 23	Data Structure 030: Number of Tests [RT041]
RT042	Table 41	IBT0001 Coding System Reference Table [RT042]
RT043	Table 29	Version Table (Special Testing) [RT043)
Retired	Table 8	Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 1 Through 9 [RETIRED]
Retired	Table 11	Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested and Found Negative [RETIRED]

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