ISBT 128 STANDARD

Technical Specification

Version 5.9.0

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This Standard is intended for the use of those implementing ISBT 128, regulatory agencies, and software developers and other manufacturers that support end-users. National Guidelines describing its use in a particular country may be an additional source of information for the end-user. If such Guidelines exist, they must be consulted because there are options in ISBT 128, and country-specific information pertaining to the particular use of such options will only be found in such Guidelines.

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Table of Contents

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TABLES

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FIGURES

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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 medical products of human origin (MPHO): blood, cellular therapy, tissues, regenerated tissue, milk, fecal microbiota, topical products of human origin, in vivo diagnostic MPHO, and organs for transplant, as well as those plasma derivatives 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. Locations of reference tables not found in this document may be found in Table 37 [RT036], page 177.

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 anyone interested in ISBT 128, including:

- 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 medical products of human origin
- Vendors of containers for blood and cellular therapy products
- Vendors of products that utilize ISBT 128
- Regulators and auditors

1.4 Normative References

ICCBBA:

ISBT 128 Standard, Standard Terminology for Medical Products of Human Origin (ST-002)
ISBT 128 Standard, Labeling of Human Tissues (ST-003)
ISBT 128 Standard, Labeling of Cellular Therapy Products (ST-004)
ISBT 128 Standard, Labeling of Blood Components (ST-005)
ISBT 128 Standard, Labeling of Ocular Tissue (ST-009)
ISBT 128 Standard, Product Description Code Database (ST-010)
ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT I28 (ST-011)
ISBT 128 Standard, ISBT 128 and the Single European Code (SEC) (ST-012)
ISBT 128 Standard, Labeling of Human Milk Banking Products (ST-013)
ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules (ST-015)

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

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Other Standards and Guidelines:

American National Standards Institute (ANSI):

ANSI MH10.8.2:2010, Data Identifier and Application Identifier Standard (18 May 2010)

European Union:

Directive 2004/23/EC of the European Parliament and of the Council
Commission Directive 2006/86/EC
Commission Directive (EU) 2015/565

International Standards Organization (ISO):

ISO/IEC 646 Information technology – ISO 7-bit coded character set for Information Interchange

ISO 3166-1 Country Codes

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

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

ISO/IEC 15415:2011(E): Information technology—Automatic identification and data capture techniques — Bar code print quality test specification — Two-dimensional symbols.

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 15459-4-2014(E): Information technology – Automatic identification and data capture techniques – Unique Identification—Part 4 Individual products and product packages

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

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

Other:
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.

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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. A subscription email notification system is available on the ICCBBA Website. The following listing is current as of the date on the front cover of this document.

Implementation Guidance Material

Implementation Guide:

Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution (IG-010)
Use of Data Matrix Symbols with ISBT 128 (IG-014)
Use of the Manufacturers Data File (IG-015)
Manufacturer's Catalog Number and Lot Number (Items Other Than Containers) (IG-019)
Encoding Product Information [Data Structures 003, 032, 033, and 034] – Tissues (IG-020)
Use of Product Code [Data Structure 003] – Blood (IG-021)
Product Coding [Data Structure 003 and 032] – Cellular Therapy (IG-022)
Use of Product Divisions [Data Structure 032] (IG-023)
Use of Flexible Date and Time [Data Structure 031] (IG-024)
Use of Dimensions [Data Structure 029] (IG-026)
Use of Red Cell Antigens with Test History [Data Structure 030] (IG-027)
Choosing an On-Demand Label Printer (IG-029)
Use of the Processing Facility Information Code [Data Structure 033] (IG-031)
Use of Product Code [Data Structure 003] – Ocular Tissue (IG-032)
Use of the Donation Identification Number [Data Structure 001] (IG-033)
ISBT 128 Facility Identification Number (IG-034)
Use of ISBT 128 in Resource-Limited Countries (IG-041)
Assigning a Patient Identification Number (JP-004)

Technical Bulletins

Bulletin 5: Bar Code Scanner Implementation of ISBT 128 Concatenation (IG-008)
Bulletin 8: Specification for ISBT 128 Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification (IG-011)
Bulletin 9: Blood Bag Identification Using ISBT 128 and GS1 (IG-012)
Bulletin 10: Valid and Invalid Bar Codes for use in ISBT 128 Validations (IG-013)

Technical Notes

Note 1: Case Conversion (IG-016)
Note 2: Length of the Product Code Bar Code and Concatenation (IG-017)

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Introductory Materials

ISBT 128 for Blood Components, An Introduction (IN-003)
ISBT 128 for Cellular Therapy, An Introduction (IN-005)
ISBT 128 for Tissues, An Introduction (IN-007)
ISBT 128, An Introduction to Bar Coding (IN-009)
ISBT 128 for Human Milk, An Introduction (IN-031)
An Introduction to ISBT 128
English (IN-015)
Arabic (IN-017)
Chinese (IN-019)
French (IN-021)
Russian (IN-023)
Spanish (IN-026)
Portuguese (IN-028)

Non-ICCBBA:

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

ISO/IEC 15459-2:2015(E): Information technology — Unique identifiers — Part 2: Registration procedures

ISO/IEC 15459-3:2015(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 medical products of human origin (MPHO) 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 MPHO. 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 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.

The ISBT 128 Standard must meet the needs of its users, and those users come from a wide variety of facilities in many countries. These facilities include highly complex and large blood centers and less complex operations in small organiztions. A guidance document has been developed for users in developing countries that addresses those aspects of ISBT 128 that are most pertinent to them. Users from developing countries are encouraged to read *Implementaiton Guide: Use of ISBT 128 in Resource-Limited Countries* (IG-041).

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1.7 Changes in this Version

The following table indicates the major changes between Version 5.8.0 and Version 5.9.0. 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 5.8.0 vs. Version 5.9.0

	Version 5.8.0 Chapter, Section, Table, or Figure	Version 5.9.0 Chapter, Section, Table, or Figure	Change	Rationale
1.	2.4.1	2.4.1	Added that the DIN can be assigned to an embryo formed via assisted reproductive technology.	To address unique donation identification for reproductive products.
2.	2.4.1	2.4.1	Included that flag character values are part of the DIN data structure.	For completeness.
3.	2.4.3	2.4.3	Added that ICCBBA should be consulted prior to national authorities assigning national codes.	To help facilitate standardization.
4.	**2.4.3**	**2.4.3**	**Added additional condition for when the ds portion of the product code shall be set to 00.**	**Proposal 17-002**
5.	**2.4.32**	**2.4.32**	**Expanded the purpose of the Product Divisions Data Structure and added clarification on what a division code may represent.**	**Proposal 17-002**
6.	2.4.32	2.4.32	Removed the requirement that the Product Divisions Data Structure shall not be used for cellular therapy and regenerated tissue products at this time.	The requirement is outdated and is no longer appropriate.
7.	**2.4.32**	**2.4.32**	**Removed the requirement that dddddd shall not be 000000.**	**Proposal 17-002**

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	Version 5.8.0 Chapter, Section, Table, or Figure	Version 5.9.0 Chapter, Section, Table, or Figure	Change	Rationale
8.	Table RT018		Removed Table RT018 and relocated it to the ICCBBA website.	For ease in expansion of the table since this table is also being utilized by GS1 for patient identification numbers.
9.	Table RT058		Removed Table RT058 and relocated it to the ICCBBA website.	For ease in expansion of the table when creating new categories of MPHO.
10.	7.5.1.1	7.5.1.1	Updated example on the printing of check characters.	The previous example (applied to the GRID) no longer applies.
11.	Table RT002	Table RT002	For Data Structure 039, corrected the check character specification from Required to Not applicable.	Correction.

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2 Data Structures

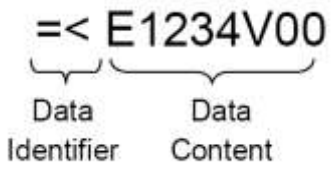
Data structures defined in this document are internationally agreed entities for encoding information relevant to MPHO. Data structures define the technical characteristics necessary for the interpretation of the information. They specify the context and structure and provide the links to the appropriate 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 identifier: a two or three-character code that identifies the data structure (described in more detail in Section 2.1) and
- 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



Data characters are the individual ASCII characters that make up the data content.

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 structure to convey similar information, systems shall be in place to ensure accurate entry of data so 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 identifier may be omitted provided that the message definition unambiguously indicates that the field contains a specific ISBT 128 data structure.

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Each ISBT 128 data structure shall have two or three 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 MH10.8.2:2010) 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 "&", and a second character from the range a-z shall be reserved for non-ICCBBA defined data structures (see section 0). The data identifier pairs &; and &! shall be hybrid structures which have an ICCBBA-defined context but a non-ICCBBA-defined structure.

The characters used as the second character of the ISBT 128 data identifiers are shown in Table 1, page 16, together with their ASCII values. All ICCBBA documents shall use the US ASCII mapping shown in Table 1 using characters defined in ISO/IEC 646. 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.

Some ICCBBA internationally-defined data structures shall have a third data identifier that shall be an alphanumeric character.

Data identifiers for ISBT 128 data structures are as indicated in Table 2, beginning on page 18.

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

ASCII Value	Character	Name
33	!	exclamation mark
34	"	inch, double quotation mark
35	#	number sign
36	$	dollar sign
37	%	percent 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

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2.2 The Role of Data Identifiers in ISBT 128 Bar Codes

As shown in Figure 1, ISBT 128 bar codes comprise two elements: a data identifier 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 content 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 Blood Groups [ABO and RhD] [Data Structure 002] bar code for an A, RhD positive unit reads as:

=%6200

where “=%” are the data identifier characters indicating that this is Blood Groups [ABO and RhD] data structure, and “6200” are the data values for A, RhD Positive with no information encoded concerning C, c, E, e, K, or Miltenberger phenotypes.

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

=\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 a blood group for the unit as A, RhD positive.

2.3 Data Structure Index

An index of data structures is provided in Table 2, beginning on page 18, which cross references them to their descriptions in this document.

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Table 2 Index of Data Structures [RT003]

Number	Data Structure Name	Number of Char-acters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value		
001	Donation Identification Number	2	=	61	A-N P-Z 1-9	65-78 80-90 49-57	N/A	N/A	αppppyynnnnnnff	2.4.1
002	Blood Groups [ABO and RhD]	2	=	61	%	37	N/A	N/A	ggre	2.4.2
003	Product Code	2	=	61	<	60	N/A	N/A	αooootds	2.4.3
004	Expiration Date	2	=	61	>	62	N/A	N/A	cyyjjj	2.4.4
005	Expiration Date and Time	2	&	38	>	62	N/A	N/A	cyyjjjhhmm	2.4.5
006	Collection Date	2	=	61	*	42	N/A	N/A	cyyjjj	2.4.6
007	Collection Date and Time	2	&	38	*	42	N/A	N/A	cyyjjjhhmm	2.4.7
008	Production Date	2	=	61	}	125	N/A	N/A	cyyjjj	2.4.8
009	Production Date and Time	2	&	38	}	125	N/A	N/A	cyyjjjhhmm	2.4.9

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Character	ASCII Value	Character	ASCII Value	Character	ASCII Value		
010	Special Testing: General	2	&	38	(	40	N/A	N/A	zzzzz	2.4.10
011	Special Testing: Red Blood Cell Antigens **[RETIRED]**	2	=	61	{	123	N/A	N/A	aaaaaaaaaaaaaaaaii	2.4.11
012	Special Testing: Red Blood Cell Antigens -- General	2	=	61	\	92	N/A	N/A	aaaaaaaaaaaaaaaaii	2.4.12
013	Special Testing: Red Blood Cell Antigens -- Finnish	2	&	38	\	92	N/A	N/A	aaaaaaaaaaaaaaaaii	2.4.13
014	Special Testing: Platelet HLA and Platelet Specific Antigens	2	&	38	{	123	N/A	N/A	AAAABBBBCCCCCCCCDE	2.4.14
015	Special Testing: HLA-A and -B Alleles **[RETIRED]**	2	=	61	[	91	N/A	N/A	EEEEFFFFGGGGHHHHLM	2.4.15

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Character	ASCII Value	Character	ASCII Value	Character	ASCII Value		
016	Special Testing: HLA-DRB1 Alleles **[RETIRED]**	2	=	61	"	34	N/A	N/A	IIIIJJJJMMMMMMMMMM	2.4.16
017	Container Manufacturer and Catalog Number	2	=	61	)	41	N/A	N/A	bqqwwwwwww	2.4.17
018	Container Lot Number	2	&	38	)	41	N/A	N/A	xxxxxxxxxx	2.4.18
019	Donor Identification Number	2	=	61	;	59	N/A	N/A	αppppvvvvvvvvvvvvvvv	2.4.19
020	Staff Member Identification Number	2	=	61	'	39	N/A	N/A	αppppuuuuuu	2.4.20
021	Manufacturer and Catalog Number: Items Other Than Containers	2	=	61	-	45	N/A	N/A	NNOOOOOOOO	2.4.21

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Character	ASCII Value	Character	ASCII Value	Character	ASCII Value		
022	Lot Number: Items Other Than Containers	2	&	38	-	45	N/A	N/A	PPPPPPPPPP	2.4.22
023	Compound Message	2	=	61	+	43	N/A	N/A	aabbb	2.4.23
024	Patient Date of Birth	2	=	61	#	35	N/A	N/A	aayyyymmdd	2.4.24
025	Patient Identification Number	2	&	38	#	35	N/A	N/A	aallxx…xx	2.4.25
026	Expiration Month and Year	2	=	61	]	93	N/A	N/A	yyyymm	2.4.26
027	Transfusion Transmitted Infection Marker	2	&	38	“	34	N/A	N/A	nnnnnnnnnnnnnnnnnn	2.4.27
028	Product Consignment	2	=	61	$	36	N/A	N/A	αppppyynnnnnccdd	2.4.28

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Char-acters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Char-acter	ASCII Value	Char-acter	ASCII Value	Char-acter	ASCII Value		
029	Dimensions	2	&	38	$	36	N/A	N/A	nnaabbbbccccccdee …aabbbbccccccdee	2.4.29
030	Red Cell Antigens with Test History	2	&	38	%	37	N/A	N/A	nnnpppppprrss… pppppprrss	2.4.30
031	Flexible Date and Time	2	=	61	(	40	N/A	N/A	ZUTTYYYYMMDD hhmm	2.4.31
032	Product Divisions	2	=	61	,	44	N/A	N/A	dddddd	2.4.32
033	Processing Facility Information Code	2	&	38	+	43	N/A	N/A	nnnnnpppppp	2.4.33
034	Processor Product Identification Code	2	=	61	/	47	N/A	N/A	nnnnnpppppqqqqq	2.4.34
035	MPHO Lot Number	3	&	38	,	44	1	49	xxxxxxxxxxxxxxxxx	2.4.35
036	MPHO Supplemental Identification Number	3	&	38	,	44	2	50	xxxxxxxxxxxxxxxxx	2.4.36

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Character	ASCII Value	Character	ASCII Value	Character	ASCII Value		
037	Global Registration Identifier for Donors **[RETIRED]**	3	&	38	,	44	3	51	nnnnaaaaaaaaaaaaaaa	2.4.37
038	Single European Code (SEC)	3	&	38	,	44	4	52	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	2.4.38
039	Global Registration Identifier for Donors	2	&	38	:	58	N/A	N/A	nnnnaaaaaaaaaaaaaabb	2.4.39
N/A	Data Structures Not Defined by ICCBBA	2	&	38	a-z	97-122	N/A	N/A	These data identifiers may be assigned by a facility or a regional, national, or supranational authority	2.5.1

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Table 2 Index of Data Structures [RT003] (continued)

Number	Data Structure Name	Number of Characters in Data Identifier	First Character of the Data Identifier		Second Character of the Data Identifier		Third Character of the Data Identifier		Data Content	See Section
			Character	ASCII Value	Character	ASCII Value	Character	ASCII Value		
N/A	Reserve Data Identifiers for a Nationally-Specified Donor Identification Number	2	&	38	;	59	N/A	N/A	Defined nationally	2.5.2
N/A	Confidential Unit Exclusion Status Data Structure	2	&	38	!	33	N/A	N/A	Defined nationally	2.5.3

N/A = Not applicable

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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 (DIN) that is a unique identification of:
  (1) a donation event [collection or recovery];
  (2) a product pool;
  (3) for plasma derivatives, a unique identification of an aliquot from a pooled plasma derivative product; and
  (4) a fertilized oocyte/embryo formed through ART.
- flag character values

The DIN shall be globally unique for 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	alphanumeric {0–9}, {A–H, J–N, P, R–Y}

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

αpppp shall specify the Facility Identification Number (FIN) of the organization that assigned the DIN 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

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yy shall specify the last two digits of the year in which the DIN was assigned. *Note: In practice, this is the "nominal" year. To cut down on wastage, DIN 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.*

nnnnnn shall specify a sequence number indicating the collection or recovery event, product pool, or aliquot from a pooled plasma derivative product, within the given year for the facility identified by the FIN

ff are "flag characters." Use of flag characters "ff" shall conform to national guidelines, if such guidelines exist. As shown in Table 3 on page 83, there are three general types of usage:

- Type 1: Two-character code used for process control and defined by ICCBBA
- Type 2: Two-character code used for process control, but locally defined
- Type 3: A two-character code used to convey a weighted ISO/IEC 7064 modulo 37-2 check character that is calculated on the thirteen-character DIN within the bar code following the process described in Sections A.1 and A.2 of Appendix A. This code within the flag characters acts on the DIN as a secondary check within the bar code itself. This differs from the check character shown within the box in Figure 2 in that the latter checks the keyboard (typed) entry of a DIN, while the code within the flag characters checks the scanned DIN.

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 *Implementation Guide: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution* (IG-010) available on the ICCBBA Website.

As shown in Figure 2, the combination, αppppyynnnnnn, forms the DIN. Flag characters, while part of the Donation Identification Number Data structure, are not a part of the DIN itself.

A keyboard entry check character is also not part of the DIN, but is calculated from the DIN and printed in human-readable format (see Section 7.5). Both the flag characters and the check character are intended for process control and are not part of the unique identification of the product.

See *Implementation Guide: Use of the Donation Identification Number [Data Structure 001]* (IG-033) for further information.

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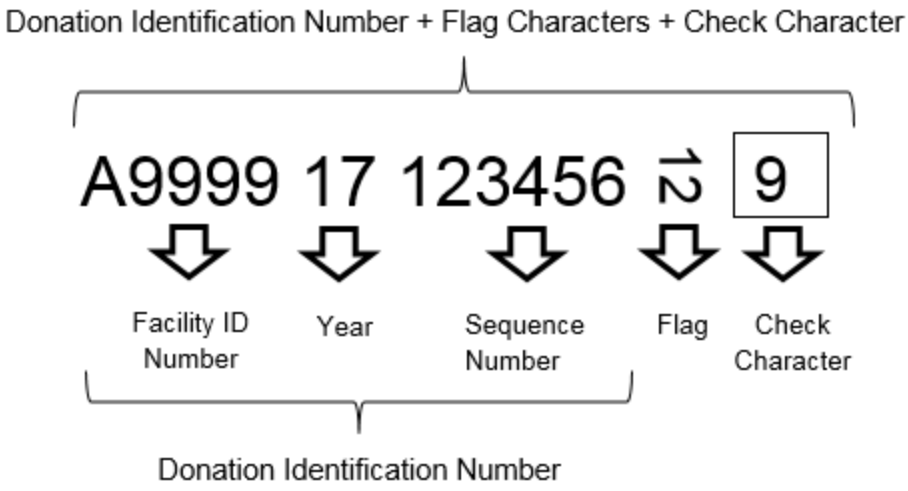
Figure 2 Donation Numbering



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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 collection

OR

- Shall convey special messages such as the status of a collection, restrictions on use, 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 collection information and shall be encoded and interpreted by reference to Table 4, page 84

OR

specify a range of special messages as shown in Table 5, page 88

r shall specify Rh and Kell or Miltenberger phenotypes and shall be encoded and interpreted by reference to Table 6, page 89. 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)

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2.4.3 Product Code [Data Structure 003]

Purpose: Data Structure 003 shall:

- identify a product intended for human use
- optionally encode information about the type of collection
- 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}
oooo	4	alphanumeric {A-Z; 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 (PDC) 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 Section 5.1).

α shall specify the following product groups:

- E or F – Blood Components
- H – MPHO with INN and/or USAN names
- M – Other Therapies (partially assigned):
  - Human milk – codes beginning with M0 (M0001 to M0999)
  - Not assigned – codes beginning with M1 through M8 (M1000 to M8999)
  - Topical products of human origin – codes beginning with M9 (M9000 to M9999)
- N – Partially assigned:
  - Organs for Transplant – codes beginning with N0 (N0001 to N0999)
  - Not assigned – codes beginning with N1 through N9 (N1000 to N9999)
- P – Regenerated Tissue Products

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- R – Partially assigned
  - Reproductive Tissue – codes beginning with R0 (R0001 to R0999)
  - Not assigned – codes beginning with R1 through R9 (R1000 to R9999)
- S – Cellular Therapy Products
- T – Tissues
- V – Ocular Tissue
- W – Partially assigned
  - Fecal Microbiota – codes beginning with W0 (W0001 to W0999)
  - Not assigned – codes beginning with W1 through W9 (W1000 to W9999)
- X – Other Blood Products
  - Plasma Derivatives – codes beginning with X0 (X0001 to X0999)
  - Not assigned – codes beginning with X1 through X4 (X1000 to X4999)
  - In vivo diagnostic MPHO – codes beginning with X5 (X5000 to X5999)
  - Not assigned – codes beginning with X6 through X9 (X6000 through X9999)
- A–D – National or local/facility codes (see below).

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

*Note: While values of **α** have previously specified a single type of product (e.g., S was always a cellular therapy product), this is no longer the case. For example, only the first 999 values of M (values beginning with M0) have been reserved for human milk. Codes beginning with M1-M8 may be assigned in the future to other products, and M9 codes (M9000 to M9999) have been assigned to products for topical use (supporting encoding of products such as serum eye drops).*

A-D National or Local/Facility Codes

The block of PDCs beginning with the alpha characters A-D (A0000-D9999 and AAAAA-DZZZZ) shall be reserved for use as nationally-defined 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/facility 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 an international code versus a nationally- or locally/facility-defined code, the user should contact the ICCBBA office.

Where such codes are used, the facility shall ensure that definitions are provided for use within their service region and that products bearing

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such codes are not transferred outside their normal distribution network. Care shall be taken in interpreting the product description from a local/facility code as this will be specific to the supplier. Software systems reading a national or local/facility code should ensure that they interpret the code taking into account the source country/facility.

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

Codes with α equal to A-C followed by alpha characters:
Codes with α equaling A-C, and alpha characters in positions 2-5 (e.g., AE134, BT123, CRA12), shall be reserved as national codes. A national authority should assign/approve nationally-defined Product Description Codes to ensure products in different categories (e.g., blood, cells, tissues, organs, and human milk) do not use the same Product Description Codes for different products.

Because on-going coordination of the assignment of nationally-defined Product Description Codes across product categories may be challenging in some countries, a country may define blocks of codes for different product categories (i.e., reserve one block of codes for blood products and another block for tissue products). National authorities or bodies should contact the ICCBBA office to help determine if the use of a national code is appropriate or whether a standardized international code should be assigned by ICCBBA.

Codes with α equal to D followed by alpha characters:

Codes with α equaling D, and alpha characters in positions 2-5 (e.g., DAX12), shall be reserved as locally/facility-defined codes.

Codes with α equal to A-D followed by numeric characters:

National agencies may reserve a range of these values in the block A-D followed by numbers (e.g., A0002 or D0111) 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/facility code as this will be specific to the supplier.

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tds

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

If **α** is E, F, or X0, then:

t shall specify the type of collection and shall be encoded and interpreted by reference to Table 7, page 90.

ds shall specify information as to whether the unit has been divided.

- If the unit has not been divided, and the Product Divisions [Data Structure 032] is not being used, **ds** shall be set to the default value of 00 (zero, zero).
- If divisions are encoded in the Product Code,

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

s shall encode the second level 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 Figure 3. Also see *Implementation Guide: Use of Product Code Data Structure [003] - Blood* (IG-021) for examples of use.

If **α** is H, S, or P, then:

t shall specify the type of collection and shall be encoded and interpreted by reference to Table 7, page 90

ds shall specify information as to whether the unit has been divided.

- If the unit has not been divided, and the Product Divisions [Data Structure 032] is not being used, **ds** shall be set to the default value of 00 (zero, zero).
- If the Product Divisions [Data Structure 032] is used, **ds** shall be set to 99. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded.
- If divisions are encoded in the Product Code:

d may encode the first division. First level divisions (up to 26) of the primary collection shall be encoded using capital letters (but see note in text box below).

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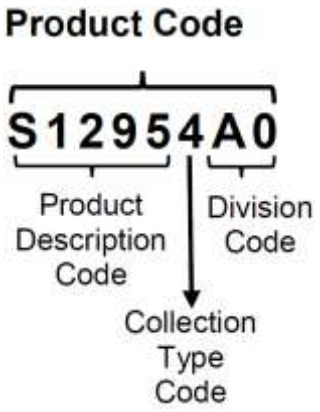
s may encode the second division. Second level subdivisions (up to 26) shall be encoded using lower-case letters (but see note in text box below).

Divisions need not be equal and this nomenclature does not require this.

*Note: If **α** is S or P, until the Product Divisions [Data Structure 032] is implemented, d and s may be used to uniquely identify divisions without regard to hierarchical level. Facilities utilizing this option shall ensure that each product is uniquely identified (i.e., multiple products with the same DIN and Product Description Code shall have a unique Division Code).*

See Figure 3. Also see *Implementation Guide: Product Coding [Data Structure 003 and 032] - Cellular Therapy* (IG-022) for examples of use.

Figure 3 Product Code Data Content for Blood, Cellular Therapy, Regenerated Tissue, or MPHO with an INN and/or USAN Name



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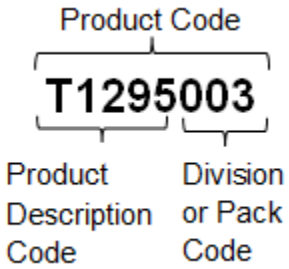
If **α** is M, N, R, T, V, or W, **tds** shall specify a 3-digit number of divisions (or packs) of the product. If the product has not been divided (or there are not multiple product packs with the same Product Description Code and DIN), **tds** shall be set to 000 (zero, zero, zero).

See Figure 4. Also see *Implementation Guide: Use of Product Code [Data Structure 003] - Tissues* (IG-020) for examples of use.

Figure 4 Product Code Data Content for Tissues (including Ocular), Milk, Organs, Reproductive, Topical Products, and Fecal Microbiota



If **α** is X1-X9, 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 nationally- or locally/facility-defined code assignment.

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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 medical devices with a human tissue component or 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 number within the calendar year (Julian date) on which the item expires

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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 number within the calendar year (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.

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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 number within the calendar year (Julian date) on which the product was collected or recovered

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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 number within the calendar year (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.

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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 data structure may have been used for blood, tissue, or cellular therapy products, Data Structure 009 should 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 number within the calendar year (Julian date) on which the product was produced

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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 number within the calendar year (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.

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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 Section 5.2, page 113) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

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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 91 and Table 11, page 97.

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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 (see glossary), CMV antibody, IgA, Parvovirus B19, Hemoglobin S, and/or a nationally-specified characterisic 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 93 and Table 12, Page 98.

Common Rh antigens may be encoded together as a phenotype (Rh column 1 on Table 9, page 93) 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 9.1, page 134.

If there are Red Blood Cell antigens test results that cannot be encoded using Table 9 or 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 Section 2.4.30, page 67.

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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 (see glossary), 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 95 and Table 13, page 99.

If there are Red Blood Cell antigens test results that cannot be encoded using Table 9 or 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 Section 2.4.30, page 67.

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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, IgA status, and anti-A and -B for platelet products. If genomic typing is used, only the first two digits of the type shall be encoded.

Structure: &{AAAABBBBCCCCCCCCDE

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}
D	1	numeric {0–9}
E	1	numeric {0–9}

The eighteen (18)-character data content string, **AAAABBBBCCCCCCCCDE**, shall be encoded and interpreted as follows:

AAAA shall specify HLA-A antigens and shall be encoded and interpreted according to Table 14, beginning on page 100.

BBBB shall specify HLA-B antigens and shall be encoded and interpreted according to Table 14, beginning on page 100.

Two **AA** values shall be encoded, followed by two **BB** values. To conform to practice the lower value shall always be listed first. See Examples of Use in Section 9.2, page 135.

CCCCCCCC shall specify platelet-specific antigens, IgA antigen and CMV antibody status and shall be encoded and interpreted according to Table 15, page 102.

D shall be reserved for future use. A default value of 0 (zero) shall be used at this time

E shall specify information about high titered antibodies to A and B antigens and shall be encoded and interpreted according to Table 16, page 103.

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

Data Structure 015 should not be used. It was **RETIRED** in Version 4.1.0 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 Section 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 4.1, page 109. 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.

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

L shall specify the CMV antibody status (see Table 17, page 104)

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

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

Data Structure 016 should not be used. It was **RETIRED** in Version 4.1.0 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 Section 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 4.1, page 109.

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.

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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; a-z, 0–9}
qq	2	alphanumeric {A–Z; 0–9}
wwwwwww	7	alphanumeric {A–Z; a–z; 0–9}*

*When used as a unique device identifier (UDI) for medical devices, only upper case alphas may be used in compliance with ISO/IEC 15459-4.

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:

- The character “1” shall be reserved for the primary collection container.
- Other numbers and upper case alpha characters may be used as container manufacturers choose.
- For an entire set of integrally attached containers, the character “y” shall be used. This code may appear on a set wrapper or individual container.
- For cartons containing blood collection containers, the character “z” shall be used. This code may appear on a packaging carton containing many sets of a given type. *[Note: This does not change the recommendation (see Chapter 8, page 133) for the use of GS1 in labeling of shipping containers. The ISBT 128 identifier would be an additional identifiers.]*
- Remaining lower case alphas are reserved for future use.

qq shall specify the identity of the container set manufacturer and is encoded and interpreted from Table W1, Manufacturer Identifier Codes (described in Section 4.2, page 109)

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

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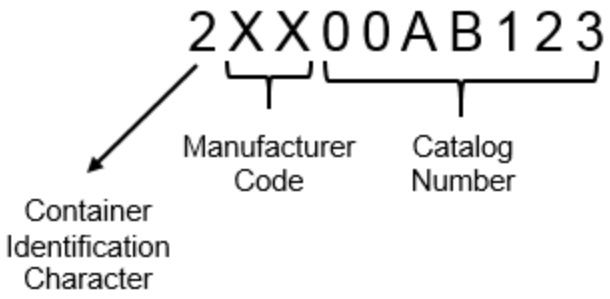
padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 0027QzE)

Used in conjunction with the Manufacturer's Data file [see Chapter 11, page 141 and *Implementation Guide: Use of the Manufacturers Data File* (IG-015)], 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.

Figure 5 Container Manufacturer and Catalog Number Data Content



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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}*

*When used as a unique device identifier (UDI) for medical devices, only upper case alphas may be used in compliance with ISO/IEC 15459-4.

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).

This data structure shall be used in conjunction with Data Structure 017.

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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 Section 5.3, page 114) published and maintained by ICCBBA in the password-protected area of the ICCBBA Website

vvvvvvvvvvvvvvv shall specify either a nationally- or facility- assigned sequence number identifying the donor. The interpretation of the assigned number requires knowledge of how such numbers are assigned in the country of the facility specified by the FIN. If the number assigned is less than sixteen (16) characters, it shall be padded with zeroes at the beginning of the string (i.e., the sequence 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.

Note: This is not the same as the Global Registration Identifier for Donors (GRID). (See Section 2.4.37, page 78)

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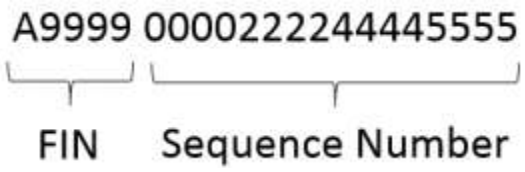
Figure 6 Donor Identification Number



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 (iccbba@iccbba.org).

Note: There is an alternative nationally-defined data structure that may be used for a donor identification number (see Section 2.5.2, page 82).

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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 5.3, page 114) 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 less than 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)

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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 4.2, page 109)

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)

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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).

This data structure shall be used in conjunction with Data Structure 021.

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

- a three-digit number referencing an entry in an ICCBBA maintained table that defines the sequence of the data structures within a compound message (see Table W2, [RT017] ICCBBA-Specified Compound Messages described in Section 4.3, page 109)

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

Rules for constructing compound messages:

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

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

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

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

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

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

ICCBBA-specified compound messages are defined in Table W2, ICCBBA-Specified Compound Messages (described in Section 4.3, page 109). While ICCBBA now encourages the use of undefined messages, requests for additional entries may be submitted to the ICCBBA office (tech.manager@iccbba.org).

Reading software should be able to interpret both unspecified sequence and specified sequence compound messages. The software should always verify the integrity of the data string, including checking that the correct number of data structures appears and, when specified sequence messages are used, that the sequence of data structures is correct. Data should only be interpreted if the integrity of the relevant data structures has been confirmed.

For examples of its use see *Implementation Guide:Use of Data Matrix Symbols with ISBT 128* (IG-014),

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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 RT018.

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* (IG-011) for examples of use.

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2.4.25 Patient Identification Number [Data Structure 025]

Note: Patient Identification should preferably be implemented by using GS1 standards, in particular when facilities are implementing Patient ID, or have already implemented Patient ID for processes other than transfusion. Data Structure 025 is maintained to support those users who have already implemented an ISBT 128 patient identification number. See Assigning a Patient Identification Number (JP-004). ISO/TS 18530:2014 should be referenced for an identifier that would be unique globally.

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 RT018.

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

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* (IG-011) for examples of use.

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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

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2.4.27 Transfusion Transmitted Infection Marker [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 105. Currently only values in the first ten positions have been defined; therefore positions 11-18 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
- ni No information encoded. Additional information may be present in accompanying documentation.

The information shall be specific to a particular collection 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 Section 9.3, page 137.

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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 Section 5.3, page 114) 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

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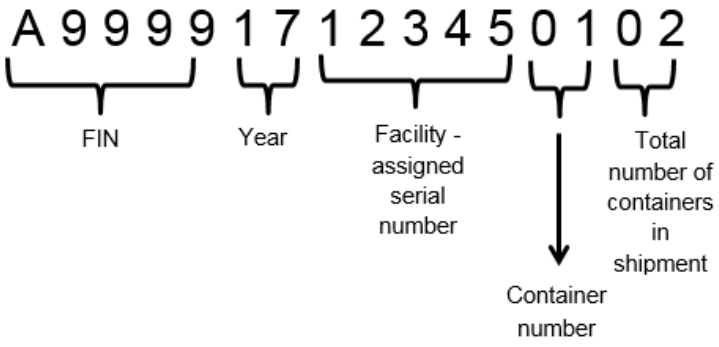
Figure 7 Example of Data Content for Data Structure 28



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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…aabbbbccccccdee

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 107

bbbb Refers to a dimension as defined by the Table 20, page 107

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 107

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 DIN to which it corresponds. It is strongly recommended that a

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Compound Message [Data Structure 023] that incorporates both the DIN and Dimensions Data Structures be used (see Section 2.4.23, page 57).

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 repeating 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 Guide: Use of Dimensions [Data Structure 029]* (IG-026), on the ICCBBA Website.

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

Purpose: Data Structure 030 shall transfer information about red cell antigen phenotypes (see glossary), 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…ppppprrss

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 listed in the table described in 4.4, page 110. The blood group system number should be listed first, followed by the antigen number.

rr Result interpretation as defined by Table 22, page 108

ss Number of tests as defined by Table 23, page 108

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 DIN to which it corresponds. It is strongly recommended that a Compound Message [Data Structure 023] that incorporates both the DIN and the

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Red Cell Antigen with Test History Data Structures be used (see Section 2.4.23, page 57).

Reading software should always verify the integrity of the data string, including checking that the correct number of repeating 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 Guide: Use of Red Cell Antigens with Test History [Data Structure 030] (*IG-027) on the ICCBBA Website.

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2.4.31 Flexible Date and Time [Data Structure 031]

Purpose: Data Structure 031 shall convey information about date and time, including the type of time (collection, recovery, production, cross clamp, etc.) and the time zone (local or UTC).

Date of Implementation: For cellular therapy, regenerated tissue, ocular tissue, and organs, this structure is available for use immediately. For other categories of product, this data structure is not an option yet to allow software developers to create, and users to validate, software capable of reading and interpreting the data structure. When it becomes available to these facilities, this document will be updated.

Structure: =(ZUTTYYYYMMDDhhmm

Element	Length	Type
=	1	data identifier, first character
(	1	data identifier, second character
Z	1	numeric {0–9}
U	1	numeric {0–9}
TT	2	numeric {0–9}
YYYY	4	numeric {0–9}
MM	2	numeric {0–9}
DD	2	numeric {0–9}
hh	2	numeric {0–9}
mm	2	numeric {0–9}

The 16-character data string, **ZUTTYYYYMMDDhhmm**, shall be encoded and interpreted as follows:

Z Shall specify local or UTC time interpreted from Table 24, page 108

U Shall be reserved for future use. The value shall be set to 0.

TT Shall specify the type of time interpreted from Table 25, page 108

YYYY Shall specify the year

MM Shall specify the month (01-12)

DD Shall specify the day (01-31)

hh Shall specify the hour (00-23)

mm Shall specify the minute (00-59)

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2.4.32 Product Divisions [Data Structure 032]

Purpose: Data Structure 032 shall convey information about:

- Aliquots, or
- One or more individual collections from the donor within the same donation event.

The division code may represent:

- one of the subunits from a single container that has been divided. This can also be referred to as an aliquot or a split.
- one of the containers from a collection where the volume of product collected required the use of more than one container.
- a single collection into one container.

Date of implementation depends on the data structure with which it will be used. That is:

When used in conjunction with Data Structure 003: Because this data structure becomes part of the unique identification of a product, implementation of the data structure must be coordinated so that computer systems of facilities receiving the product are able to scan and interpret the codes.

The data structure may be used for cellular therapy or regenerated tissue products if:

- A product will remain within the facility that labeled it with this data structure
- There is an agreement between supplier and receiver of a product to utilize this data structure sooner

When used in conjunction with Data Structure 034: This data structure may be used at any time.

*Note: At the present time, use of the Product Divisions Data Structure with Data Structure 003 is restricted to cellular therapy and regenerated tissue Product Codes (where **α** is S and P, respectively) and for products identified using Data Structure 034. However, in the future the use of the Product Divisions Data Structure may be extended to blood products (where **α** is E or F).*

Structure: =,dddddd

Element	Length	Type
=	1	data identifier, first character
,	1	data identifier, second character
dddddd	6	alphanumeric {A–Z, 0–9}

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The 6-character data string, **dddddd**, shall be encoded and interpreted as follows:

dddddd shall specify the Division Code

The Division Code allows for a high level of flexibility.

- Digits shall be used where a single level of divisions is required (allowing up to 999,999 divisions).
- If it is desirable to show levels of divisions (to allow for divisions of divisions), alpha characters shall be used. In this situation, the six character field may be split into three pairs, each allowing AA through to ZZ. This provides up to three levels of division.

When the Product Divisions Data Structure is used in conjunction with the Product Code [Data Structure 003], "99" shall appear in the 7th and 8th positions of the Product Code. See Section 2.4.3. The Product Divisions Data Structure, when used, is essential for traceability. Software shall require that when a 99 appears in positions 7 and 8 of the Product Code [Data Structure 003], the Product Divisions Data Structure shall be scanned and recorded. If manual records are maintained, the Divisions Code shall be recorded along with the DIN and the Product Code for all records needed for traceability.

Each Product Divisions code shall be unique for a given Product Code [Data Structure 003] and DIN.

For use of this data structure in conjunction with the Product Code [Data Structure 003] see *Implementation Guide, Use of Product Divisions [Data Structure 032]* (IG-023)

For use of this data structure in conjunction with the Processor Product Identification Code [Data Structure 034], see *ISBT 128 Standard, Coding and Labeling of Medical Devices using ISBT 128* (ST-011).

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2.4.33 Processing Facility Information Code [Data Structure 033]

Purpose: Data Structure 033 shall convey information about the facility that assigned the Product Code and may include a Facility-defined Product Code assigned by the processing or labeling facility.

Structure: &+nnnnnppppppp

Element	Length	Type
&	1	data identifier, first character
+	1	data identifier, second character
nnnnn	5	alphanumeric {A–N, P–Z, 0–9}
pppppp	6	alphanumeric {A–Z, 0–9}

The 11-character data string, **nnnnnpppppp**, shall be encoded and interpreted as follows:

nnnnn shall specify the Facility Identification Number, or the FIN (P), of the facility that assigned the Product Code and is encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the Product Code may, or may not, be the same facility that assigned the DIN.

This code, in conjunction with the DIN [Data Structure 001] and Product Code [Data Structure 003], may be required for unique identification of the product. If the FIN within Data Structure 033 is required to ensure unique identification of the product, then these data structures shall be presented in a 2-D symbol to ensure all information required for traceability is read. See *Implementation Guide: Use of Processing Facililty Information Code [Data Structure 033]* for an explantation of when the FIN(P) is required for traceability.

pppppp shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the product within its system. The FPC shall not be used to create uniqueness for the product. The processing or labeling facility may choose to publish reference tables for use by the organizations receiving the product. If a value is not required, the default value 000000 (zeroes) shall be used.

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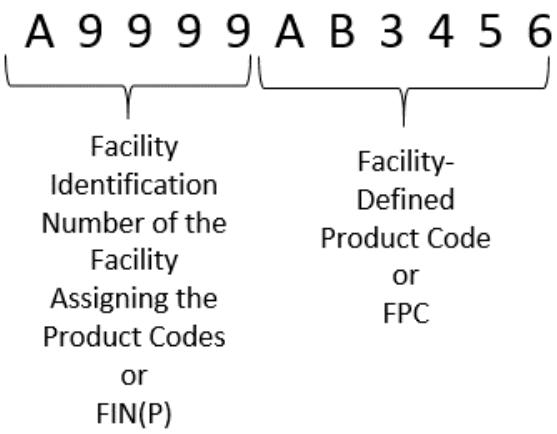
Figure 8 Example of Data Content for Data Structure 033



See *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033]* (IG-031) for more information.

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2.4.34 Processor Product Identification Code [Data Structure 034]

Purpose: Data Structure 034, the Processor Product Identification Code (PPIC), shall identify the processing or labeling facility, a Facility-defined Product Code (FPC), and a standardized Product Description Code (PDC). This data structure may be used for medical device identification.

Structure: =/nnnnnpppppqqqqq

Element	Length	Type
=	1	data identifier, first character
/	1	data identifier, second character
nnnnn	5	alphanumeric {A–N, P–Z, 0–9}
pppppp	6	alphanumeric {A–Z, 0–9}
qqqqq	5	alphanumeric {A–Z, 0–9}

The 16-character data string, **nnnnnpppppqqqqq**, shall be encoded and interpreted as follows:

nnnnn shall specify the Facility Identification Number, or the FIN(P), of the facility that assigned the PDC and shall be encoded and interpreted by reference to the ICCBBA Registered Facility table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website. The facility that assigned the PDC may, or may not, be the same facility that assigned the DIN.

pppppp shall specify a Facility-defined Product Code (FPC) assigned by the processing or labeling facility indicating a catalog or other number that identifies the product within its system. This code shall not be used to create uniqueness for the product. If a value is not required, the default value 000000 (zeroes) shall be used. This facility may choose to publish reference tables for use by the organizations receiving the product.

qqqqq 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.

Medical devices with a human donor component shall be uniquely identified using Data Structure 034, the Donation Identification Number [Data Structure 001], and Product Divisions [Data Structure 032].

See *ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT I28* (ST-011) for more information.

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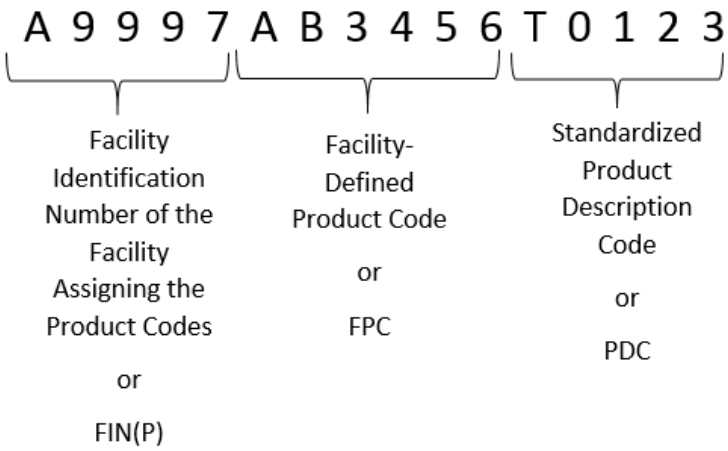
Figure 9 Example of Data Content for Data Structure 034



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2.4.35 MPHO Lot Number [Data Structure 035]

Purpose: Data Structure 035 shall be used for the lot number of medical products of human origin

Structure: &,1xxxxxxxxxxxxxxxxx

Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
1	1	data identifier, third character
xxxxxxxxxxxxxxxxx	18	alphanumeric {A–Z; 0–9}

The data content string shall be 18 characters and shall be encoded and interpreted as follows:

xxxxxxxxxxxxxxxxx Facility-defined lot number

The 18-character data content string, **xxxxxxxxxxxxxxxxx**, shall encode the processor's lot number. If the lot number is less than 18 characters, it shall be padded with zeroes at the beginning of the string (i.e., the lot number 5434RZ would be transmitted as 0000000000005434RZ).

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 zero.

This data structure shall not be used to uniquely identify a product.

When used as part of a production identifier in the labeling of a medical device, this data structure must comply with ISO 15459-4.

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2.4.36 MPHO Supplemental Identification Number [Data Structure 036]

Purpose: Data Structure 036 shall be used for a supplemental identification number for MPHO

Structure: &,2xxxxxxxxxxxxxxxxxx

Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
2	1	data identifier, third character
xxxxxxxxxxxxxxxxxx	18	alphanumeric {A–Z; 0–9}

The data content string shall be 18 characters and shall be encoded and interpreted as follows:

xxxxxxxxxxxxxxxxxx Facility-defined identification number

The 18-character data content string, **xxxxxxxxxxxxxxxxxx**, shall encode the processor's supplemental identification number. If the number is less than 18 characters, it shall be padded with zeroes at the beginning of the string (i.e., the supplemental identification number 1234RZ would be transmitted as 000000000001234RZ).

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

This data structure shall not be used to uniquely identify a product.

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2.4.37 Global Registration Identifier for Donors (Retired) [Data Structure 037]

Data Structure 037 shall not be used. It was retired in version 5.8.0 of the *ISBT 128 Technical Specification*. It was replaced with Data Structure 039.

Purpose: Data Structure 037 is no longer used – see Data Structure 039.

Structure: &,3nnnnaaaaaaaaaaaaaa

Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
3	1	data identifier, third character
nnnn	4	numeric {0–9}, first character shall not be 0
aaaaaaaaaaaaaaa	15	alphanumeric {A–Z; 0–9}

The data content string shall be 19 characters and shall be encoded and interpreted as follows:

nnnn GRID Issuing Organization Number (ION) that shall be encoded and interpreted by reference to the ICCBBA GRID Issuing Organization Number table published and maintained by ICCBBA in the password-protected area of the ICCBBA Website.

aaaaaaaaaaaaaaa Donor Identifier that shall specify a sequence number identifying a donor, potential donor, or registry listing for cord blood stem cell products within the registration organization.

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2.4.38 Single European Code [Data Structure 038]

Purpose: Data Structure 038 shall encode the Single European Code (SEC) as described in the EU Commission Directive 2015/565.

Structure: &,4xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

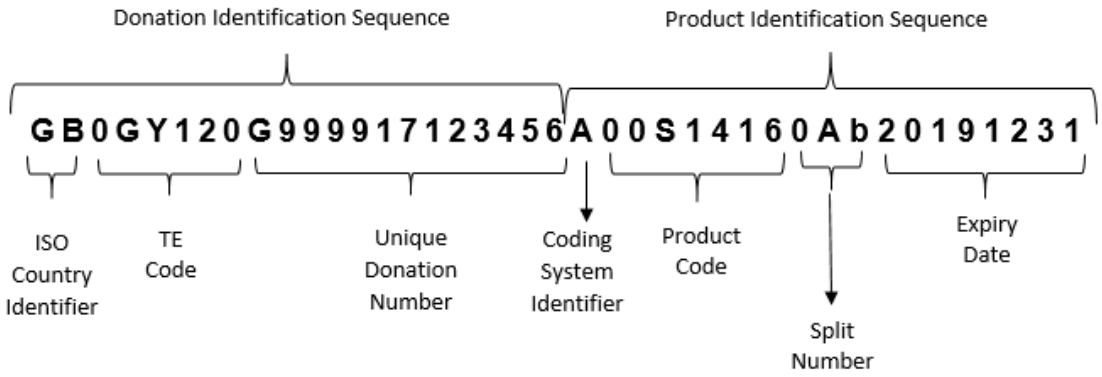
Element	Length	Type
&	1	data identifier, first character
,	1	data identifier, second character
4	1	data identifier, third character
xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	40	alphanumeric {A–Z; a-z; 0–9}

The data content string shall be 40 characters and shall be encoded and interpreted as follows:

xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	The SEC as described in EU Commission Directive 2015/565.

The data content comprises two segments: the Donation Identification Sequence and the Product Identification Sequence. See Figure 10. This use of this data structure is described in detail in *ISBT 128 Standard, ISBT 128 and the Single European Code (SEC)* (ST-012).

Figure 10 Example of Data Content for Single European Code [Data Structure 038]



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2.4.39 Global Registration Identifier for Donors [Data Structure 039]

Purpose: Data Structure 039 shall specify a globally unique identifier for HPC donors or potential donors. This replaces Data Structure 037.

Structure: &:nnnnaaaaaaaaaaaaabb

Element	Length	Type
&	1	data identifier, first character
:	1	data identifier, second character
nnnn	4	numeric {0–9}, first character shall not be 0
aaaaaaaaaaaaa	13	alphanumeric {0–9} Where alpha characters are used they must be uppercase.
bb	2	two-digit checksum {00–36}

The data content string shall be 19 characters and shall be encoded and interpreted as follows:

nnnn GRID Issuing Organization Number (ION) that shall be encoded and interpreted by reference to the ICCBBA GRID Issuing Organization Number table published and maintained by ICCBBA on the ICCBBA Website.

aaaaaaaaaaaaa Registration Donor Identifier that shall uniquely identify a donor, or potential donor, within the registration organization. (Note: Alpha characters in the RDI will increase the length of the linear bar code.)

bb Two-digit modulus 37-2 checksum.

See *ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules* (ST-015) for additional requirements when assigning a GRID.

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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 (FINs) 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/facility- or nationally-assigned Product Description 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].

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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 Section 2.4.19, page 52).

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.		

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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 sequence number — value is assigned as 60 plus the modulo 37-2 checksum
97–99	Reserved for future assignment
Alphanumeric using numbers in the range 0-9 and alphas in the range A-N, P, R-Y	Reserved for future assignment

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Table 4 Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of 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

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

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
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
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

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

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
Group A, Pooled RhD [Pooled Products]	A0							
Group B, Pooled RhD [Pooled Products]	B0							
Group AB, Pooled RhD [Pooled Products]	C0							
Group O, Pooled RhD [Pooled Products]	D0							
Pooled ABO, RhD Positive [Pooled Products]	E0							
Pooled ABO, RhD Negative [Pooled Products]	F0							
Pooled ABO, Pooled RhD [Pooled Products]	G0							
Pooled ABO (RhD not specified) [Pooled Products]	H0							
A_1	I0							
A_2	J0							

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

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
A_1B	K0							
A_2B	L0							

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Table 5 Data Structure 002: Special Messages [RT006]

gg	Interpretation
00	No ABO or Rh information is available
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.

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

Results with Anti-Kell:			**Phenotype:**			
No Information	**Negative**	**Positive**	**C**	**c**	**E**	**e**
0	S	T	**No Information**	**No Information**	**No Information**	**No Information**
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	**No Information**	negative	**No Information**

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 for K, C, c, E, and 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.

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

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

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

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)

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

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)

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

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.

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Table 9 (continued) Data Structure 012: Special Testing: Red Blood Cell Antigens — General [RT009]
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.

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

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)

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Table 10 (continued) Data Structure 013**:** Special Testing: Red Blood Cell Antigens — Finnish [RT010]
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)

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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_0	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.

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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_0	39	Lu^b	64	removed	89	Wr^a
15	CE	40	Lu3	65	Hy	90	Ge4
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	Nationally specified
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

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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_0	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

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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
		B58	58
		B59	59
		B60	60
		B61	61

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

HLA-A	Value of AA	HLA-B	Value of BB
		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

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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-15a**	**HPA-6bw**	**HPA-15b**	**HPA-7bw**	**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)

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Table 16 Data Structure 014: Special Testing: Platelet HLA and Platelet Specific Antigens, Position 18 [RT044]

Value	Titer status for antibody to A and/or B antigens
0	Not tested
1	High titered anti-A and -B not detected
2	Reserved for future use
3	Reserved for future use
4	Reserved for future use
5	Reserved for future use
6	Reserved for future use
7	Reserved for future use
8	Reserved for future use
9	No information

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Table 17 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

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Table 18 Data Structure 027: Transfusion Transmitted Infection Marker [RT019]
Positions 1 through 9

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	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni	ni
1	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg
2	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos
3	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni	neg	ni
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	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni	pos	ni
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; ni — No information encoded. Additional information may be present in accompanying documentation.

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Table 19 (continued) Data Structure 027: Transfusion Transmitted Infection Marker [RT019]
Positions 10 through 18

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

neg — negative; pos — positive; ni — No information encoded. Additional information may be present in accompanying documentation.

Note: Positions 11 through 18 have been reserved for future use.

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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	1E9	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
0011	rings	Length of trachea expressed in number of rings

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

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

Value	Meaning
01	Negative – Test methodology not specified
02	Positive – Test methodology not specified
03	Negative – Serological testing
04	Positive – Serological testing
05	Negative – Predicted phenotype based on genotyping
06	Positive – Predicted phenotype based on genotyping

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

Value	Meaning
01	Tested once on this collection
02	Tested once on prior collection
03	Tested ≥ twice on different collections (current and historic) with concordant results
04	Tested ≥ twice on different collections (historic only) with concordant results
05	Tested ≥ twice on this collection only, different samples, with concordant results
06	Test history not specified.

Table 24 Data Structure 031: Time Zone [RT045]

Value	Meaning
1	Local time zone of facility assigning the date
2	Coordinated Universal Time (abbreviated UTC)

Table 25 Data Structure 031: Type of Time [RT046]

Value	Meaning
01	Expiration date and time
02	Collection date and time
03	Production date and time
04	Cross Clamp date and time
05	Time of preservation
06	Time of death of donor

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4 Reference Tables Maintained on Websites

4.1 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, which is part of the European Molecular Biology Laboratory. 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 Version 4.1.0 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.

While use in the labeling of new products is not recommended, 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

4.2 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

4.3 Table W2 Data Structure 023: ICCBBA-Specified 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

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4.4 Data Structure 030: Red Cell Antigens with Test History

There are multiple tables supporting this data structure, and all are maintained by the Working Party on Red Cell Immunogenetics and Blood Group Terminology of the International Society of Blood Transfusion (ISBT) and posted on their website: http://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology/.

This website also includes instructions for requesting an ISBT number for an antigen.

4.5 Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number, Location Code Table [RT018]

This table is maintained on the ICCBBA Website at:

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

4.6 Facility Type Codes Used in the Registered Facilities Database Table [RT058]

This table is maintained on the ICCBBA Website at:

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

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5 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, or change too frequently, to be maintained as simple tables in this document.

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.

5.1 Product Description Codes

There shall be a single ISBT 128 Product Description Code database for all types of products. These products shall have assigned prefix character(s) as shown in Table 26 that permit individual tables to be extracted.

Table 26 Product Categories and Assigned Prefixes

Product Category	Assigned Prefix Character(s)
Blood	E or F
MPHO with INN and/or USAN names	H
Milk	M0
Topical Products of Human Origin	M9
Organs for Transplant	N0
Regenerated Tissue	P
Reproductive Tissue	R0
Cellular Therapy	S
Tissues	T
Ocular Tissue	V
Fecal Microbiota	W0
Plasma Derivatives (for which blood group is significant)	X0
In Vivo Diagnostic MPHO	X5

The Product Description Code forms the first five characters of the eight-character Product Code [Data Structure 003] and the last five characters of the 16-character Processor Product Identification Code [Data Structure 034].

A product in the ISBT 128 database shall be defined by a unique combination of the characteristics. Each such combination shall be given a five-character Product Description Code, the first character(s) of which shall identify the different product types (E, F, H, M0, M9, N0, P, R0, S, T, V, W0, X0, or X5, as noted in Table 26), and the remaining characters shall provide a unique sequence number. These codes shall be maintained in a table in the database named ISBT 128 Product Description Code Database. The Product Description Code shall identify a product by mapping, via the Product Description Codes table, to the unique combination of Class, Modifier, and Attribute(s) characteristics, which are referenced in the associated database tables.

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.

.

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Details of the database structure may be found in *ISBT 128 Standard, Product Description Code Database* (ST-010).

All Product Description Code database tables shall be published in the password-protected area of the ICCBBA Website. This file is a Microsoft Access® file and is named:

ISBT 128 Product Description Code Database

More information about use of the Product Description Code database for different product categories may be found in the following documents:

- *Encoding Product Information [Data Structures 003, 032, 033, and 034] – Tissues* (IG-020)
- *Use of Product Code [Data Structure 003], Blood* (IG-021)
- *Product Coding [Data Structure 003 and 032], Cellular Therapy* (IG-022)
- *Use of the Product Code [Data Structure 003], Ocular Tissue* (IG-032)
- *Coding and Labeling of Medical Devices Using ISBT I28* (ST-011)

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5.2 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

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.

For additional screening/testing, details of the test methodology and status are not encoded unless otherwise stated in the definition. Such details may be included in accompanying documentation.

Table 27 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.
DEFINITION	255		Definition of the interpretation. This field is optional.

Table 28 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

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5.3 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

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

Table 29 Registered Facilities [RT030]

Field Name	Field Size	Field Description
FIN	5	Facility Identification Number*
Firm Name	100	Legal name of facility
City	60	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
Alternative Name	100	A second name associated with the facility
Country ISO	2	Code for country as assigned in ISO 3166-1*
Facility Type	80	Indicates category or categories of products the facility manages

*10 FINs have been set aside for validation purposes. These are A9990-A9999. ICCBBA has used the user-defined country code of XA (as allowed by ISO 3166-1) for these FINs.

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5.4 GRID Issuing Organization Identification Number

This Microsoft Excel® spreadsheet contains the names and locations of all GRID Issuing Organizations. It is published on the ICCBBA Website and is called:

GRID Issuing Organizations – xlsx

An XML file and its associated XML Schema are also available on the ICCBBA Website:

GRID Issuing Organizations Data File – xml
GRID Issuing Organizations XML Schema – xsd

Note: *The XML data file contains ION*s *that have an "Active" status only while the Excel spreadsheet provides both "Active" and "Inactive" IONs.*

Version number related information is also provided in the XML file. Version numbers for the database table shall be derived as described in Appendix B.

The information about each organization held in the ICCBBA database is provided by the World Marrow Donor Association (WMDA) at the time of listing. It is the responsibility of the Issuing Organization to ensure that it remains accurate by notifying WMDA of any changes. WMDA will, in turn, notify ICCBBA of changes.

For more information, incuding the structure of the database tables, see *ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules* (ST-015).

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6 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.

6.1 Linear Symbols

6.1.1 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.

6.1.2 Symbol Print Quality

Following methodology 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.

6.1.3 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.

For ISBT 128 linear barcodes on a container label, the target X dimension is 0.25 mm, and the minimum X dimension is 0.17mm.

Any use of an ISBT 128 data structure as a linear printed bar code other than on a container label should use an X dimension that meets these criteria. However, in situations in which this recommendation is still too large to allow labeling of specific usage, a nominal X dimension of ≥0.127 mm may be used, provided it has been verified that this dimension is compatible with the instruments that will be reading the barcode.

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

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

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

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 should 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 10).

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6.2 2-D Symbols

6.2.1 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.

6.2.2 Symbol Print Quality

Following methodology described in ISO/IEC 15415, print quality shall be 1.5/6/670 where 1.5 is the overall quality, 6 is the measuring aperture reference number (corresponding to a 0.15 mm diameter aperture) and 670 is the peak response wave length in nanometers.

6.2.3 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.

6.2.4 Reading and Interpreting Information

A single data structure may be encoded in a Data Matrix symbol. The data structure shall be encoded as it would be within a linear bar code: data identifier followed by the data content.

To encode multiple data structures within a Data Matrix symbol, software should be written to ensure that the full data string matches the information provided in the Compound Message data structure and Table W2, ICCBBA-Defined Compound Messages described in Section 4.3, page 109.

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* (IG-014).

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6.3 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.

6.4 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 12.

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7 Product Labeling

7.1 Specific Product Labeling

For information on labeling of specific products, see

- *ISBT 128 Standard, Labeling of Blood Components* (ST-005)
- *ISBT 128 Standard, Labeling of Cellular Therapy Products* (ST-004)
- *ISBT 128 Standard, Labeling of Human Tissues* (ST-003)
- *ISBT 128 Standard, Labeling of Ocular Tissue* (ST-009)
- *ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT 128* (ST-011)
- *ISBT 128 Standard, Labeling of Human Milk Banking Products* (ST-013)

7.2 National Labeling Guidelines

National bodies may publish guidelines for labeling which adhere to the ISBT 128 Standard. 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.manager@iccbba.org).

7.3 General Principles

Two label 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. Faciliites may also apply intermediate, or in-process, labels.

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).

To assist in label design, if more than one linear bar code is to be placed in a quadrant of a 100 mm by 100 mm label, 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 6.1.3, beginning on page 116.

Examples of labels are shown in Appendix C. A library of example labels from different countries is posted on the ICCBBA Website.

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7.3.1 Minimum Information

Traceability of MPHO labeled with ISBT 128 requires, at a minimum:

1. Every ISBT 128-labeled product shall carry electronically-readable information required for traceability. This includes the DIN, the standardized Product Description Code (Data Structure 003 or 034), and a divisions/pack code (Data Structure 003 or 032). If the processing facility identification code [FIN(P)] is required for traceability, this too shall be present in an electronically-readable format (Data Structure 033 or 034). See *Implementation Guide: Use of the Processing Facility Information Code [Data Structure 033] (IG-031)* for an explanation of when the FIN(P) is required for traceability.

2. Every ISBT 128-labeled product shall carry text corresponding to the required electronically-readable information.

   The information in 1 and 2 above should appear on the affixed label whenever possible.

   If linear bar codes are used and the affixed label is too small to carry the required bar codes, then the DIN bar code shall appear on the affixed label, along with text for the DIN, Product Description Code, and divisions/pack code. On the attached or accompanying documentation, the DIN, Product Description Code (Data Structures 003 or 034), and divisions/pack code (Data Structure 003 or 032) shall be present in both electronically-readable and eye-readable format.

   If the FIN(P) is required for traceability, a 2-D symbol shall be used. The DIN shall be present in electronically-readable and eye-readable format on the affixed label. The Product Description Code, a divisions/pack code, and the FIN(P) shall be encoded in the 2-D symbol. Text corresponding to the information in the 2-D symbol should be present on the affixed label. If space does not permit this, a 2-D symbol with corresponding text information shall be present on attached or accompanying documentation.

   Additional information may be required based on product category and/or country. See specific labeling documents for additional information.

7.4 Printing Label Text

Fonts selected for labels shall allow differentiation between similar characters (e.g., 0/O and 1/I).

Particular font sizes and types are not specified, but designers shall ensure clarity of all text and use larger fonts to emphasize critical information. The use of color (for example, for ABO) is neither prohibited nor encouraged.

At a minimum, data labels (i.e., text indicating the meaning of the data item) should be used when the purpose of the code is not apparent by its position on the label or by its context. See Figure 11. Appropriate abbreviations (e.g., Prod Code for Product Code) may be used when space is limited.

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Figure 11 Examples of Data Labels (in Red Boxes)

7.4.1 Donation Identification Number [001]

All data characters in the 13-character DIN shall be printed. This includes the second data identifier character as in this specific case the second data identifier character is also a data character. A national authority should determine how it should be displayed, for example:

V0043 14 499999

A123 4140 12346

7004 203 123 456

The flag characters 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 Section 2.4.1, page 25).

When the default (00) is used for flag characters, it does not have to be printed.

When Type 1 or Type 2 flag characters are used 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 DIN.

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- Non-numeric Presentation: A graphical icon or other representation of the value of “ff”. For example, for flag “07” printing, an icon showing a small test tube may be used.

Type 3 flag characters shall not be printed.

When linear bar codes are used, the DIN shall be printed beneath the corresponding bar code, but it does not need to be printed left justified. This allows the DIN to be printed in a larger font.

See Section 7.5.1.1, page 130, for printing of keyboard entry check characters.

7.4.2 Other Data Structures – Linear Bar Codes

7.4.2.1 Text Corresponding to the Data Content of Linear Bar Codes

General rules:

- Every ISBT 128 linear bar code on a container label shall be accompanied by text that corresponds to the data content, unless otherwise specified.
- Data identifiers shall not appear in the text, unless otherwise specified.
- Text corresponding to the data content shall be printed left justified (in line with the leftmost bar of the bar code) immediately below, but not touching, a linear bar code, unless otherwise specified
- Text shall be in font that differentiates similar characters with a maximum height of 2 mm.

See Figure 12.

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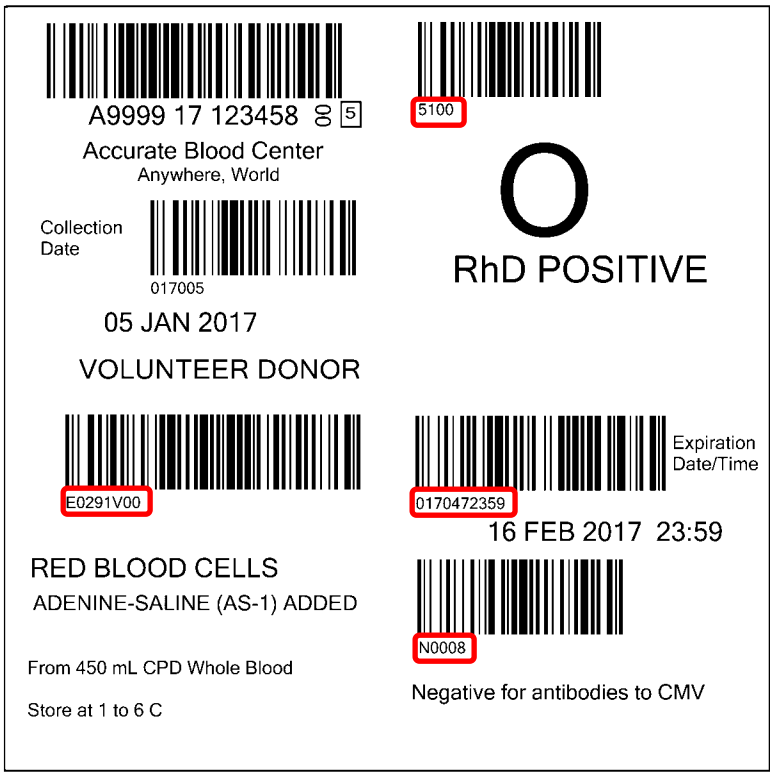
Figure 12 Text Corresponding to Data Content in a Linear Bar Code (in Red Boxes)



Exceptions to these rules are:

1. **Special Testing: Red Blood Cell Antigens [Data Structures 012 and 013]**

   For Red Blood Cell Antigens, text corresponding to the data content of the linear bar code is not required. Printing the interpretation of the electronically-readable information (e.g., C-, E-) is sufficient. This recommendation is based on the rationale that should the bar code not be scanned, it is likely that entering each antigen result will be more accurate than entering a string of 18 numbers. This is a recommendation, not a requirement, and not all computer systems may support it.

2. **Special Testing: Platelet HLA and Platelet Specific Antigens [Data Structure 014]**

   For Platelet HLA and Platelet Specific Antigens, text corresponding to the data content of the linear bar code is not required. Printing the interpretation of the electronically-readable information (e.g., HLA-A2,A19; B27,B40) is sufficient. This recommendation is based on the rationale that should the bar code not be scanned, it is likely that entering each antigen result will be more accurate than entering a string of 18 numbers. This is a recommendation, not a requirement, and not all computer systems may support it.

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3. **Container Manufacturer and Catalog Number [017] and Container Lot Number [018]**

   Information on printing text for these data structures is found in *ISBT 128 Standard, Labeling of Blood Components* (ST-005).

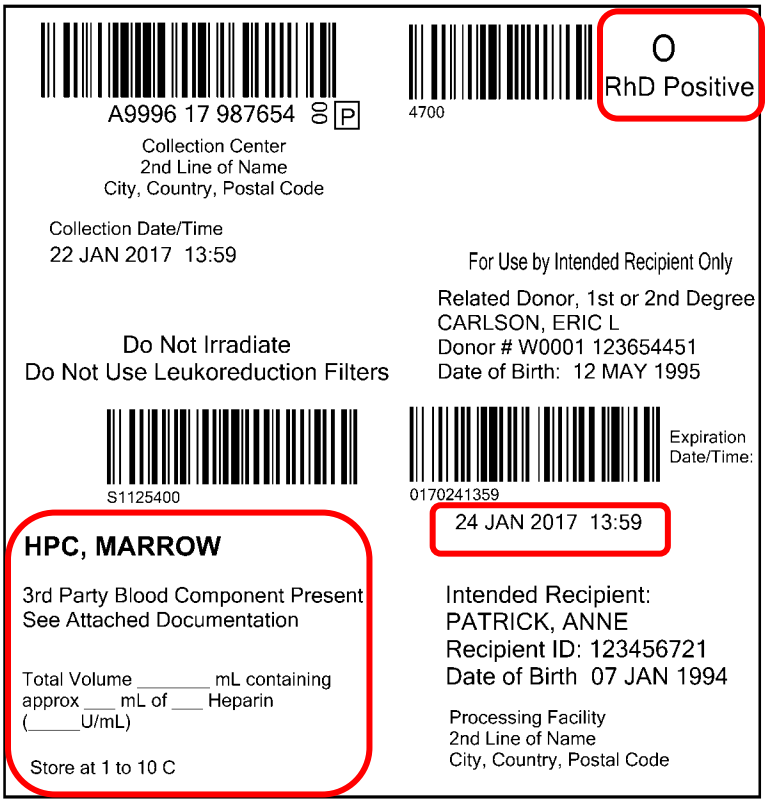
7.4.2.2 Other Text Associated with Electronically-Readable Information

Except in situations described in Section 7.4.4, other text on the label that is associated with electronically-readable information may be nationally defined to allow for differences in language, regulatory requirements, and preferences.

Text associated with electronically-readable information should appear near its corresponding bar code. 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, if permitted by regulations and pertinent standards.

See Figure 13.

Figure 13 Other Text Associated with Electronically-Readable Information (in Red Boxes)



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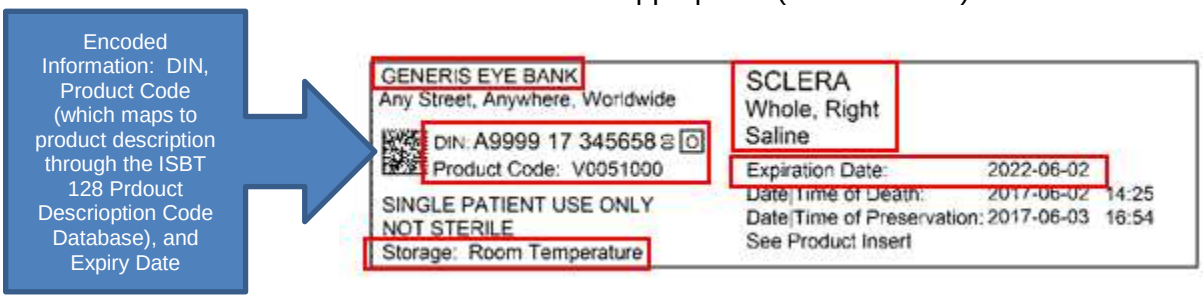
7.4.3 Other Data Structures – 2-D Bar Codes

Text corresponding to the information encoded in a 2-D bar code should 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, if permitted by regulations and pertinent standards.

Except in situations described in Section 7.4.4, text on the label that is associated with electronically-readable information may be nationally defined to allow for differences in language, regulatory requirements, and preferences.

Figure 14 Text Corresponding to Electronically-Readable Information in a 2-D Symbol with Associated Data Labels where Appropriate (in Red Boxes)



Note: In this example, the time of death and the time of preservation are not encoded in the 2-D symbol. This information could be encoded into the 2-D symbol, and if it were, this text would be considered to be text associated with information in a 2-D symbol.

7.4.4 Text Associated with Specific Data Structures

7.4.4.1 Product Descriptions [Data Structure 003]

See specific labeling standards for blood, cellular therapy, tissue, ocular tissue, medical devices, and human milk products for printing of product descriptions.

In general, product description text should be printed with the Modifier (when present) proportionally smaller than the Class name and Attribute(s) text should be proportionately smaller than Modifier text.

See Figure 15.

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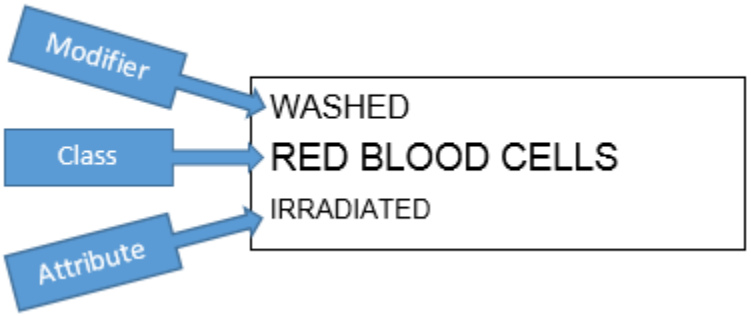
Figure 15 Relative Text Size of Class, Modifier, and Attributes



7.4.4.2 Dates and Times [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 and the month alphabetical using a three-letter abbreviation. The year shall be a four-digit numerical representation.

Expiration Date:

2017-03-17
OR
17 MAR 2017

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.

Other standards setting organizations may place additional restrictions on the eye-readable format of the date (e.g., may restrict it to the ISO 8601-2004). See product category specific or national/regional labeling guidance documents.

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 Coordinated Universal 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:

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2017-01-15 15:15 EST
(2017-01-15 15:15 UTC)
OR
15 JAN 2017 15:15 EST
(15 JAN 2017 20:15 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.

7.4.4.3 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.

2017-03
OR
MAR 2017

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

7.4.4.4 Donor Identification Number [Data Structure 019]

When the sequence number portion of the Donor Identification Number is less than 16 digits, the sequence number shall be padded with zeroes at the beginning of the actual number. If desired, software developers can routinely strip off padding and present the sequence number when displaying the number on a screen within the facility that assigned it.

For example:

In Denmark, a possible data content string would be:

V0100 000000 080656 1665

a ten (10)-digit sequence number with six (6) leading zeroes as padding. This number might display on a screen within the facility as 080656 1665. In France, it might be:

F2499 0 1 56 05 18 033 087 78

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

7.4.5 Text Not Associated with Electronically-Readable Information

Text not associated with electronically-readable information includes warnings such as “This product may transmit infectious agents”.

The placement of this information is not standardized internationally, but may be standardized nationally. Users should review national documents for additional information.

If not nationally defined, facilities may add additional text to the label where space permits and there is need.

See Figure 16.

Figure 16 Text Not Assoicated with Electronically-Readable Information (in Red Boxes)

Note: In this example, the time of death and the time of preservation are not encoded in the 2-D symbol. This information could be encoded into the 2-D symbol, and if it were, this text would be considered text associated with electronically-readable information.

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7.5 Keyboard Entry Check Character K

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

- Donation Identification Number [001]
- Donor Identification Number [019]
- Transfusion Transmitted Infection Marker [027]
- Global Registration Identifier for Donors [037]

If text corresponding to the data content of the following data structures is printed, a keyboard entry check character **K** shall be printed.

- Special Testing: Red Blood Cell Antigens [011] (retired)
- 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] (retired)
- Special Testing: HLA-DRB1 Alleles [016] (retired)

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 36 in Appendix A. For an example of the calculation for the 13-character string **αppppyynnnnnn** of the Donation Identification Number see Donation Identification Number

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.

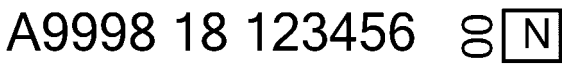
7.5.1 Other Data Structures

For other bar codes, the keyboard entry character may be used or even required (see Table 30, page 131). 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.

7.5.1.1 Printing the Check Character

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

For example, a DIN would be printed:



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

Number	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 if text corresponding to the 18-character code is printed
013	Special Testing: Red Blood Cell Antigens — Finnish	Required if text corresponding to the 18-character code is printed
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	Required if text corresponding to the 18-character code is printed
015	Special Testing: HLA-A and –B Alleles (RETIRED)	Required if text corresponding to the 18-character code is printed
016	Special Testing: HLA-DRB1 Alleles (RETIRED)	Required if text corresponding to the 18-character code is printed
017	Container Manufacturer and Catalog Number	Not applicable
018	Container Lot Number	Not applicable
019	Donor Identification Number	Required

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Table 30 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002] (continued)

Number	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
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
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	Transfusion Transmitted Infection Marker	Required
028	Product Consignment	Optional
029	Dimensions	Optional
030	Red Cell Antigens with Test History	Not applicable
031	Flexible Date and Time	Optional
032	Product Divisions	Optional
033	Processing Facility Information Code	Optional
034	Processor Product Identification Code	Optional
035	MPHO Lot Number	Optional
036	MPHO Supplemental Identification Number	Optional
037	Global Registration Identifier for Donors (RETIRED)	Required
038	Single European Code (SEC)	Not applicable
039	Global Registration Identifier for Donors	Not applicable

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8 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 bar code placed on the carton. GS1 general specifications give full detail about the data structure and the encryption into the bar code. The following example illustrates how the information is carried in a GS1-128 bar code.

Figure 17 GS1 Outer Packaging Bar Code

Technical Bulletin 9 Blood Bag Identification Using ISBT 128 and GS1 (IG-012), 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.

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9 Data Structure Coding and Decoding: Examples of Use

9.1 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:

880000008700000000

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:

679999999999999900

decodes as:

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

Example 3:

999999999999999100

decodes as:

CMV antibody negative; no other information.

Example 4:

486881355800000000

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.

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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 98, 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 text. As a further example, rather than the complete red blood cell phenotype associated with Data Structure 012, the 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.

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

Examples of Use

Refer to Table 14, beginning on page 100, Table 15, page 102, and Table 16, page 103.

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

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An individual of homozygous HLA-A2, B7 type with no information about platelet-specific antigens and with no high titered anti-A and –B detected would be coded as:

029907999999999901 (if only the phenotype is known)
020207079999999901 (if the genotype is known)

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9.3 Data Structure 027: Transfusion Transmitted Infection Marker

The Infectious Markers Data Structure allows complex testing information to be conveyed electronically (see Section 2.4.27, page 62).

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 105, as:

321415000000000000

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10 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* (IG-017) and *Technical Bulletin 5, Bar Code Scanner ISBT 128 Concatenation* (IG-008). These documents may be found on the ICCBBA Website.

10.1 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, Bar Code Scanner Implementation of ISBT 128 Concatenation* (IG-008).

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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.

10.2 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.

10.3 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.

10.4 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.

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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, Bar Code Scanner ISBT 128 Concatenation* (IG-008).

10.5 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, Bar Code Scanner Implementation of ISBT 128 Concatenation* (IG-008).

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11 Blood Container Manufacturers Information Data File Specification

11.1 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.

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11.2 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 31 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 07, i.e., this version of the data file)

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Table 32 Data Lines [RT032]

Field	Length	Format	Comment
1	max 20	alphanumeric (max 20)	ICCBBA-defined data label (see Table 34)
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 and upper case alpha characters shall be used to identify individual containers within the set. 1 shall be reserved for the primary collection container of a whole blood set.
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 33 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

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Table 34 ICCBBA-Assigned Data Labels and Content (Version 07) [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 collections (in mL)	Numeric (3)	O	N/A	Set
CONTENT	The fluid content of the container as supplied	select from ICCBBA lookup table‡	D	NONE	Container

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Table 34 ICCBBA-Assigned Data Labels and Content (Version 07) [RT034] (continued)

Data Label	Content	Format (max length)	Required *	Default Value	Application
	(anticoagulant, additive, etc.)				
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
PROCONLY CONTAINER	Indicator that this is a container suitable for in-process product only (not designed for storage of final product)	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

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Table 34 ICCBBA-Assigned Data Labels and Content (Version 07) [RT034] (continued)

Data Label	Content	Format (max length)	Required *	Default Value	Application
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 product the container is designed to hold (in mL)	Numeric (4)	O	N/A	Container
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, BFYCONTAINER , or PROCONLYCONTAINER 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, Standard Terminology for Medical Products of Human Origin* (ST-002) in the Technical Documentation area of the ICCBBA Website.

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11.3 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.

11.4 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* (IG-015). This document may be found on the ICCBBA Website.

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12 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 [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.

[RT042] specifies identifiers that may be used in encoding ISBT 128 data structures into HL7 messages. Additional lines may be added to the table upon request by contacting the ICCBBA office (tech.manager@iccbba.org).

Table 35 IBT0001 Coding System Reference Table [RT042]

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0001	2.16.840.1.113883.6.18.2.1	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)	A999908123456
IBT1-0002	2.16.840.1.113883.6.18.2.2	Flag Value	Two character code corresponding to the flag characters from an ISBT 128 Donation Identification Number [Data Structure 001]. See Table 3 [RT004] for acceptable values and their interpretation.	01

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0003	2.16.840.1.113883.6.18.1.1	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.	A99990812345601
IBT1-0004	2.16.840.1.113883.6.18.1.2	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	2.16.840.1.113883.6.18.2.3	ABO RhD	ISBT 128 two character ABO/RhD code. See Table 4 [RT005] for acceptable values and their interpretation.	51
IBT1-0006	2.16.840.1.113883.6.18.2.4	Special Messages	ISBT 128 two-character Special Message. See Table 5 [RT006] for acceptable values and their interpretation.	Mq
IBT1-0007	2.16.840.1.113883.6.18.2.5	Rh K Mur	ISBT 128 single character value corresponding to third data character of Data Structure 002 and encoding Rh, Kell and Mia/Mur phenotypes. See Table 6 Table 6 [RT007] for acceptable values and their interpretation.	B
IBT1-0008	2.16.840.1.113883.6.18.1.3	Product Code	Eight character ISBT 128 Product Code [Data Structure 003], referencing the ISBT 128 Product Description Code Database and Table 7 [RT008].	E0001V00
IBT1-0009	2.16.840.1.113883.6.18.2.6	Product Type	Five character code corresponding to the Product Code in first five characters of Data Structure 003 and the last 5 characters of Data Structure 034. It references a value in the ISBT 128 Product Description Code Database.	E0123

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0010	2.16.840.1.113883.6.18.2.7	Collection Type	Single character code corresponding to the sixth character of an ISBT 128 Product Code [Data Structure 003] and specifying collection type. See Table 7 [RT008] for acceptable values and their interpretation. Only used for blood and cellular therapy products.	V
IBT1-0011	2.16.840.1.113883.6.18.2.8	First Division	Single character code corresponding to the seventh character of an ISBT 128 Product Code [Data Structure 003] and indicating a division value or a flag to an alternative division number code. Only used for blood and cellular therapy products.	A
IBT1-0012	2.16.840.1.113883.6.18.2.9	Second Division	Single character code corresponding to the eighth character of an ISBT 128 Product Code [Data Structure 003] indicating a division value or a flag to an alternative division number code. Only used for blood and cellular therapy products.	b
IBT1-0013	2.16.840.1.113883.6.18.2.10	Division Number	Three digit code corresponding to the sixth to eighth character of an ISBT 128 Product Code [Data Structure 003]. Not used for blood or cellular therapy products. Indicates the division number of the product.	017
IBT1-0014	2.16.840.1.113883.6.18.1.4	Expiration Date	Six digit code corresponding to an expiration date as defined for ISBT 128 Data Structures 004 and 005.	008120
IBT1-0015	2.16.840.1.113883.6.18.2.11	Expiration Time	Four digit code corresponding to an expiration time as defined for ISBT 128 Data Structure 005.	1900
IBT1-0016	2.16.840.1.113883.6.18.1.6	Collection Date	Six digit code corresponding to a collection date as defined for ISBT 128 Data Structures 006 and 007.	008120

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0017	2.16.840.1.113883.6.18.2.12	Collection Time	Four digit code corresponding to a collection time as defined for ISBT 128 Data Structure 007.	1900
IBT1-0018	2.16.840.1.113883.6.18.1.8	Production Date	Six digit code corresponding to a production date as defined for ISBT 128 Data Structures 008 and 009.	008120
IBT1-0019	2.16.840.1.113883.6.18.2.13	Production Time	Four digit code corresponding to a production time as defined for ISBT 128 Data Structure 009.	1900
IBT1-0020	2.16.840.1.113883.6.18.1.10	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	2.16.840.1.113883.6.18.1.12	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	2.16.840.1.113883.6.18.1.13	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
IBT1-0023	2.16.840.1.113883.6.18.1.14	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], Table 15 [RT014], and Table 16 [RT044] for acceptable values and their interpretation.	022408279999999900

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0024	2.16.840.1.113883.6.18.1.15	Special Testing HLA- A and HLA-B Alleles	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	2.16.840.1.113883.6.18.1.16	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	2.16.840.1.113883.6.18.1.17	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.	1IC0027QZE
IBT1-0027	2.16.840.1.113883.6.18.1.18	Container Lot	Ten character code corresponding to an ISBT 128 Container Lot Number [Data Structure 018].	0000123456
IBT1-0028	2.16.840.1.113883.6.18.1.19	Donor ID	Twenty-one character code corresponding to an ISBT 128 Donor Identification Number [Data Structure 019].	W00000000000012436744
IBT1-0029	2.16.840.1.113883.6.18.1.20	Staff ID	Eleven character code corresponding to an ISBT 128 Staff Member Identification Number [Data Structure 020].	W0000016902
IBT1-0030	2.16.840.1.113883.6.18.1.21	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.	IC000RA123
IBT1-0031	2.16.840.1.113883.6.18.1.22	Other Lot	Ten character code corresponding to an ISBT 128 Lot Number: Items Other Than Containers [Data Structure 022].	0000435678

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0032	2.16.840.1.113883.6.18.1.24	Patient DOB and information location	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	2.16.840.1.113883.6.18.1.25	Patient ID and information location	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	2.16.840.1.113883.6.18.1.27	Transfusion Transmitted Infection Marker	Eighteen digit code corresponding to an ISBT 128 Transfusion Transmitted Infection Marker code [Data Structure 027]. See [RT019] for acceptable values and their interpretation.	321415000000000000
IBT1-0035	2.16.840.1.113883.6.18.1.29	One or more Dimensions	Variable length field corresponding to an ISBT 128 Dimensions [Data Structure 029]. Refer to Table 20 [RT037], Table 21 [RT038], and Table 22 [RT039]	0101000700031000
IBT1-0036	2.16.840.1.113883.6.18.1.30	Multiple Red Cell Antigens with Test History	Variable length field corresponding to multiple ISBT 128 Red Cell Antigens with their Test Histories [Data Structure 030]. Refer to Table 23 [RT040], Table 24 [RT041] and the red cell antigen nomenclature table found at http://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology/	004004002020100400402040040030103004005020 2

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0037	2.16.840.1.113883.6.18.2.14	Individual Red Cell Antigen with Test History	Ten digit code corresponding to an individual ISBT 128 Red Cell Antigen and its test history within Data Structure 030. Refer to Table 23 [RT040], Table 24 [RT041] and the red cell antigen nomenclature table found at http://www.isbtweb.org/working-parties/red-cell-immunogenetics-and-blood-group-terminology/	0040020201
IBT1-0038	2.16.840.1.113883.6.18.2.15	Individual Product Dimension	Twelve digit code corresponding to a single dimension of a product within the ISBT 128 Dimensions [Data Structure 029]. Refer to Table 20 [RT0037], Table 21 [RT038], and Table 22 [RT039]	010007000310
IBT1-0039	2.16.840.1.113883.6.18.2.16	Information Location	Two digit code corresponding to a location code identifying where the occurrence of the information was held. Refer to Table 18 [RT018]	01
IBT1-0040	2.16.840.1.113883.6.18.2.17	Patient Date of Birth	Eight digit code corresponding to an ISBT 128 Patient Date of Birth [Data Structure 024].	20011203
IBT1-0041	2.16.840.1.113883.6.18.2.18	Patient Identification Number	Variable length field corresponding to an ISBT 128 Patient Identification Number [Data Structure 025].	06923832
IBT1-0042	2.16.840.1.113883.6.18.1.31	Flexible Date and Time	Sixteen digit code corresponding to a time and date defined within the code for Data Structure 031. Refer to Table 25 [RT045] and Table 26 [RT046]	1001201311042359
IBT1-0043	2.16.840.1.113883.6.18.1.32	Product Divisions	Six character code corresponding to the ISBT 128 Product Divisions Code for Data Structure 032.	AABC00
IBT1-0044	2.16.840.1.113883.6.18.2.19	Facility Identification Number	Five character code corresponding to the ISBT 128 Facility Identification Number of the facility that assigned the Product Code and referencing a value in the ISBT 128 Registered Facilities Database [Data Structure 033 or 034]	A9999

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Table 35 IBT0001 Coding System Reference Table [RT042] (continued)

Identifier	Object Identifier (OID)	Text Name	Description	Data Example
IBT1-0045	2.16.840.1.113883.6.18.2.20	Facility Product Code	Six character code in Data Structure 033 corresponding to facility-defined product code (FPC). [Data Structure 033 or 034]	AB7878
IBT1-0046	2.16.840.1.113883.6.18.1.34	Processor Product Identification Code	Sixteen character code corresponding to (1) the ISBT 128 Facility Identification Number of the facility that processed or labeled the product, (2) a six character code corresponding to the facility-assigned product code or catalog number, and (3) a five character code corresponding to the ISBT 128 Product Description Code. Provides the UDI Device Identifier for medical devices containing medical products of human origin. [Data Structure 034]	A9999AB1234T1234
IBT1-0047	2.16.840.1.113883.6.18.1.35	MPHO Lot Number	Eighteen character code corresponding to an ISBT 128 MPHO Lot Number [Data Structure 035].	00000ABC123cba3210
IBT1-0048	2.16.840.1.113883.6.18.1.36	MPHO Supplemental Identification Number	Eighteen character code corresponding to an ISBT 128 MPHO Supplemental Identification Number [Data Structure 036].	00054321EFG123hk00
IBT1-0049	2.16.840.1.113883.6.18.1.37	Global Registration Identifier for Donors (Retired)	Nineteen character code corresponding to a Global Registration Identifier for Donors [Data Structure 037]. This has been superseded by IBT1-0051.	9999ABC123DEF000009
IBT1-0050	2.16.840.1.113883.6.18.1.38	Single European Code	Forty character code corresponding to a Single European Code [Data Structure 038].	GB0GY120G99991412345 6A00S14160Ab20161231
IBT1-0051	2.16.840.1.113883.6.18.1.39	Global Registration Identifier for Donors	Nineteen character code corresponding to a Global Registration Identifier for Donors [Data Structure 039].	**9990012070433201625**

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13 ICCBBA

13.1 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.

ICCBBA is a nongovernmental organization (NGO) in official relations with the World Health Organization (WHO).

13.2 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. 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 Identification Numbers (FINs) to facilities for use in certain data structures. The FINs are published in the password-protected area of the ICCBBA Website. An organization may have more than one FIN if it is useful for its operational needs. See *Implementation Guide: ISBT 128 Facility Identification Number* (IG-034) for further information about assignment of FINs, inactivation of FINs, the process to follow when an organization changes its name, etc.

Each vendor whose products or services include software or instrumentation that assists in the reading, storing, interpreting, transferring, printing, or other manipulation of ISBT 128 data identifiers, data structures and/or databases, any product bearing an ISBT 128 data structure (e.g. bar code, RFID tag) or any part thereof, must register with ICCBBA and pay an annual licensing fee.

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 contacting the ICCBBA office.

13.3 Global Registration Identifier for Donors (GRID) Issuing Organization Number

Each organization that needs to assign a Global Registration Identifier for Donors must maintain a registration with ICCBBA. This may be done through the WMDA following

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instructions found in *ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules* (ST-015).

13.4 Code Assignment

All codes used in ICCBBA data structures are assigned by ICCBBA, except those codes designed specifically for national or local/facility use and the Facility-defined Product Code. 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.

13.5 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**.

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Acronyms

ANSI	American National Standards Institute
ASCII	American Standard Code for Information Interchange
DIN	Donation Identification Number
EBI	European Bioinformatics Institute
EBMT	European Group for Blood and Marrow Transplantation
EDI	Electronic Data Interchange
FACT	Foundation for the Accreditation of Cellular Therapy
FIN	Facility Identification Number
FIN(P)	FIN of the facility assigning the Product Code
FPC	Facility-Defined Product Code
GRID	Global Registration Identifier for Donors
HLA	Human Leukocyte Antigen
HL7	Health Level 7
ID	Identification
IEC	International Electrotechnical Commission
IMGT	International ImMunoGeneTics project
ION	Issuing Organization Number (for GRID)
ISCT	International Society of Cellular Therapy
ISO	International Organization for Standardization
JACIE	Joint Accreditation Committee of ISCT and EBMT
MPHO	Medical Products of Human Origin
NGO	Nongovernmental Organization
PDC	Product Description Code (used for ISBT 128-defined standardized product description codes)
RFID	Radio Frequency Identification
UTC	Coordinated Universal time
WHO	World Health Organization
WMDA	World Marrow Donor Association

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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 2-D 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 text that verifies accurate keyboard entry.	
Collection Type	A designation indicating why a product was collected	
	Autologous	A product collected from an individual for his or her own use.
	Dedicated	A product collected through an arrangement by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products) when the collections occur more frequently than would normally be allowed.
	Designated	A special product (for example, HLA-compatible) collected through an arrangement by the collecting facility to be used by a specific recipient (or for Cellular Therapy products, possibly a small group of recipients).
	Directed	A product collected from an individual who presents to the collecting facility at the request of another person intending his/her product to be used by that person.
	Family reserved	A product collected from an individual that is reserved for use in the treatment of that individual or a member of his/her family with the consent of that individual or his/her representative. Crossover is not precluded if allowed by pertinent regulations, provided all necessary regulatory and consent requirements are satisfied.

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	Medical exception	A product collected from an individual who did not meet the usual eligibility criteria. Because of the special value of the product to a specified recipient (e.g., HLA type), a medical director or other authorizer has approved the collection for the specified recipient. An example would be a donor whose travel history would normally preclude him from donating. This category should not be used for biohazard collections.
	Replacement	Replacement collection is defined by national authorities rather than by ICCBBA since the definition may vary by country.
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 10 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 25.)	
Data identifier	The first two or three 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 Section 2.4.1, page 25.)	
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.	

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Donation event (collection or recovery)	The meaning of this term varies depending on the MPHO involved. National requirements should be consulted as they may provide specific guidance in the assignment of DINs.	
	Blood and cellular therapy products from peripheral blood	A single session during which whole blood or blood product(s) are collected from a donor.
	Marrow	A single session during which product(s) are collected from a donor. The session may include the use of multiple needles and/or collection containers.
	Cord blood	The collection of blood from the umbilical cord of one infant. For multiple births, the collection of blood from the umbilical cord of each child is considered a separate donation event and must be assigned a different DIN.
	Tissue and organs from a deceased donor	Two options exist: 1. The entire recovery event associated with one donor. This may include the activities of multiple recovery agencies over a period of time. In this situation, there is a national agreement that all recovery agencies will use the same DIN for a given donor. For example, over a period of time, organ, cardiac valve, ocular tissue, and musculoskeletal recovery teams obtain products from a donor. All products from this donor would have the same DIN. (This is the preferred option, where it is feasible.) 2. The recovery event associated with one donor and one recovery agency. Products collected by different recovery teams at different times would constitute separate events and each event would be assigned a different DIN. During a transition from option 1 to option 2, or by a national decision, a hybrid situation may exist (e.g., all tissues may share the same DIN, but not organs).
	Tissue or organs from a living donor	A single session during which organs or tissues are procured.
Facility	An organization that is responsible for the collection/recovery, processing, and/or distribution of ISBT 128-encoded products.	

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Flag character	Part of the data content of a data structure used in process control or data transmission checking. For ISBT 128, flag characters are used with the Donation Identification Number. 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 medical products of human origin. 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 Number.	
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 Number	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.	
Phenotype	The observable expression of the genes inherited by a person that reflects the biological activity of the genes. In ISBT 128 coding of test results, the term phenotype includes predicted phenotypes based on genotyping where there is evidence in the literature to support such a prediction.	

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Plasma Derivative	A product that contains concentrated fractions of plasma proteins that have been separated using physical-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.
Transfer container	A container intended for post-manufacturing connection to a container set.
UTC	Coordinated Universal 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.

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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 36;
2. For each character in the string determine its weighted check value by multiplying the check value from Table 36 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. The result of step 6 is the ISO/IEC modulus 37-2 checksum.
8. Using the value in Step 6, determine the check character by again referring to Table 36 (this time read the character from the value). This is the modulo 37-2 checksum character (referred to as K throughout this *Standard*).

Table 36 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		

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Example of Calculation

Donation number G1234 17 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	7	7	896
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			146178
Step 4	modulo 37 (first MOD)			28
Step 5	subtract from 38			10
Step 6	modulo 37 (second MOD)			10
ISO/IEC 37-2 checksum				10
ISBT 128 check character (K)				A

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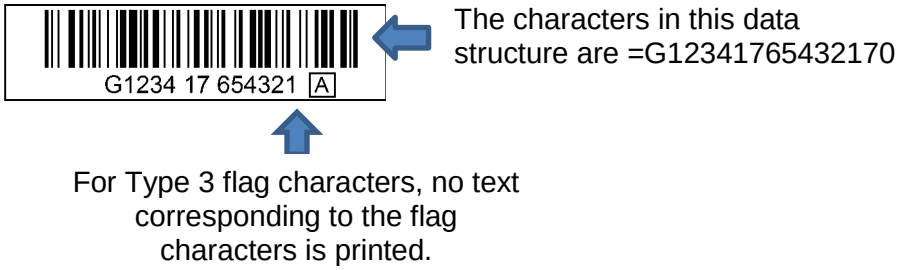
A.2 Calculating Type 3 Flag Characters

1. To calculate Type 3 flag characters, follow the steps in Section A.1 to step 7.
2. To the ISO/IEC modulus 37-2 checksum obtained in step 7 of Section A.1, add 60. This gives the Type 3 flag characters.

For example, in the example used in Section A.1 (DIN = G1234 17 654321), the ISO/IEC 37-2 checksum is 10. The Type 3 flag would be 10 + 60, or 70. Thus the data content of Data Structure 001 for this DIN would be: G12341765432170.

Because Type 3 flag characters are not printed, this would appear as shown in Figure 18.

Figure 18 Use of Type 3 Flag Characters



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A.3 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 raI...36}
case InputString[‘]’of
'“’.. '9': ISOValue := (ord(InputStrin–[I]) -‘4’);
'“’.. 'Z': ISOValue := (ord(InputStrin–[I]) -‘5’);
'*': ISOValue := 36;
end;
end {function ISOvalue};
var
J,Sum,CharValue,CheckValue : integer;
const
ISOCharTable : string[‘7] = '0123456789ABCDEFGHIJKLMNOPQRSTU’WXYZ*';
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};
```

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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 iso7064ValueToCharTabl“[] =
"0123456789ABCDEFGHIJKLMNOPQRSTU”WXYZ*";
// Read the characters from left to right.
for (sum = 0; ch = *inputString; inputString++)
{
// Ignore invalid characters as per ISO 7064.
isDigit = (('h'>= '0') && ('h'<= '9'));
isUpperAlpha = (('h'>= 'A') && ('h'<= 'Z'));
if (isDigit || isUpperAlpha)
{
// Convert the character to its ISO 7064 value.
if (isDigit)
charValue–='c' - '0';
else
charValue–='c' - '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 for providing the PASCAL function ISOmod37_2, and Mr. Harold Boe for providing the C-language function CalculateISO7064Mod37_2.

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

Databases and documents will be versioned

For documents:
ISBT 128 Standard documents shall include a version control sheet within the document. Versioning shall have a three digits and be numbered as follows:

- 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 discrete 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 to the standard or to 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 Product Description Code database shall have a three-digit version number.

- The third digit shall be increased by one if the only change to the database is the addition of Product Description Codes 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 other tables.
- The first digit shall tie the database to the controlling version of the *ISBT 128 Standard, Product Description Code Database* (ST-010). That is, if ST-010 is version 6.x.x, the database is version 6.y.y.

For Special Testing database:
The Special Testing database shall have a three-digit version number.

- 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 version of the *ISBT 128 Standard Technical Specification* (ST-001). That is, if ST-001 is version 5.x.x, the database is version 5.y.y.

For GRID Issuing Organization Number database:
The Issuing Organization Number database shall have a two-digit version.

- The second digit shall be increased by one if facilities are added or information is changed (e.g., a status becomes inactive).
- The first digit shall tie the database to the controlling version of the *ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules* (ST-015). That is, if ST-015 is version 3.x.x, the database is version 3.y.

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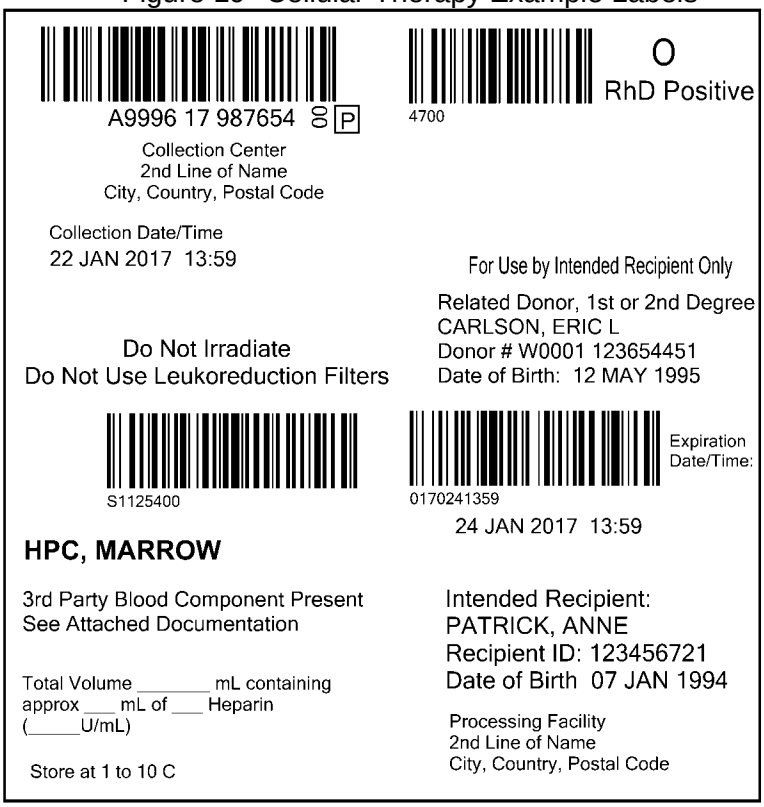
Appendix C Label Examples

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, Labeling of Blood Components* (ST-005)
- *ISBT 128 Standard, Labeling of Cellular Therapy Products* (ST-004)
- *ISBT 128 Standard, Labeling of Human Tissues* (ST-003)
- *ISBT 128 Standard, Labeling of Ocular Tissue* (ST-009)
- *ISBT 128 Standard, Coding and Labeling of Medical Devices Using ISBT I28* (ST-011)
- *ISBT 128 Standard, ISBT 128 and the Single European Code (SEC)* (ST-012)
- *ISBT 128 Standard, Labeling of Human Milk Banking Products* (ST-013)

Standardized labels for organs for transplant and reproductive tissue have not yet been designed.

Figure 19 Cellular Therapy Example Labels



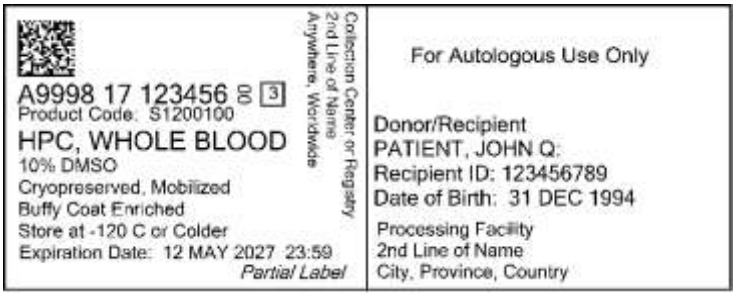


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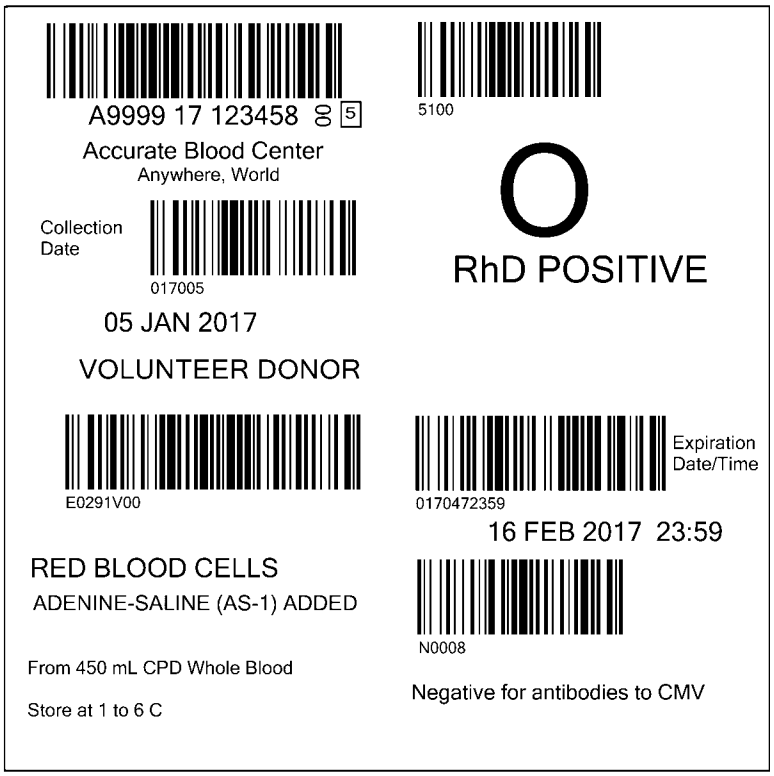
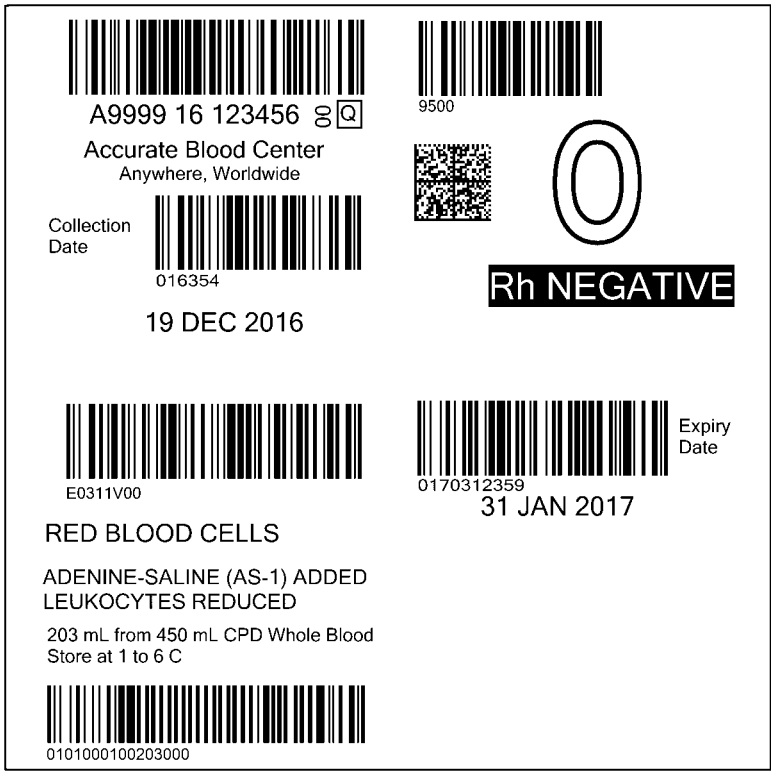
Figure 20 Blood Product Example Labels





Note: When a 2-D symbol containing information for multiple data structures is present with multiple linear bar codes, it is considered a "transition label". Transition labels allow facilities receiving products time to develop the software capacity to read and interpret 2-D symbols. In this case, the location of the 2-D symbol may be nationally-defined. In discussions of Technical Advisory Groups, the recommendation has been made to place such a 2-D symbol as close as possible to its eventual location. Thus, this example shows the 2-D symbol in the upper half of the label. This is not standardized and facilities may select a different location.

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Note: The design of a blood label with a 2-D symbol replacing a number of linear bar codes has been approved through the ICCBBA proposal process. However, computer software around the world may not be ready to read and interpret the compound message within the symbol. Therefore, the timing of implementation should be coordinated between blood suppliers and their customers. Implementation of this label format shall follow the requirements specified in the ISBT 128 Standard, Labeling of Blood Components (ST-005).

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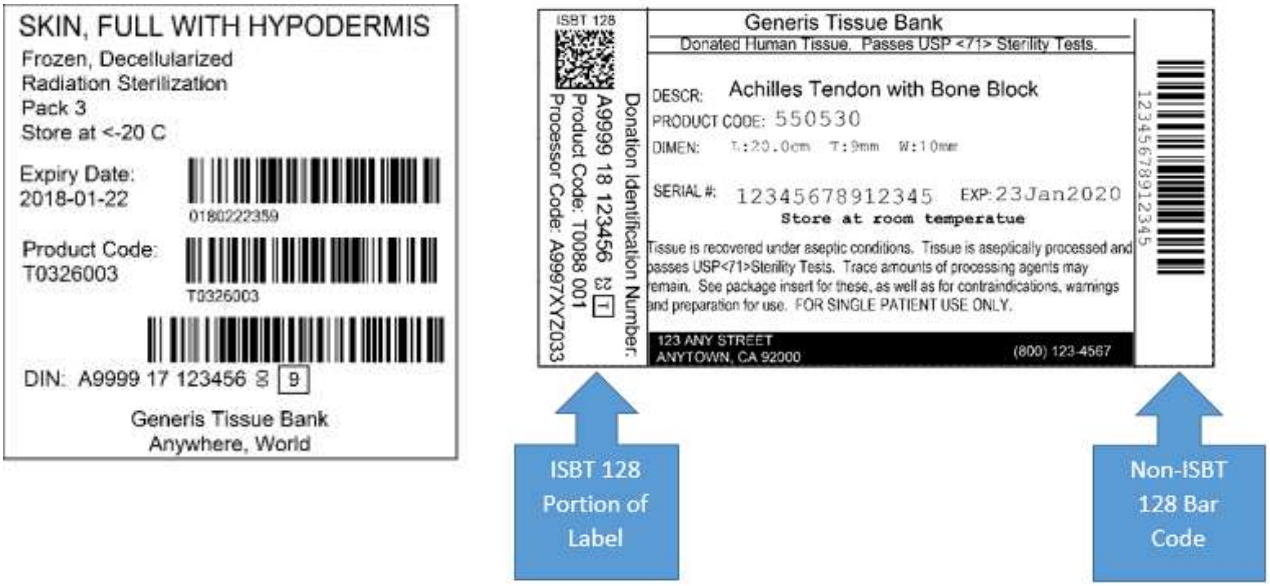
Figure 21 Human Tissue Example Labels



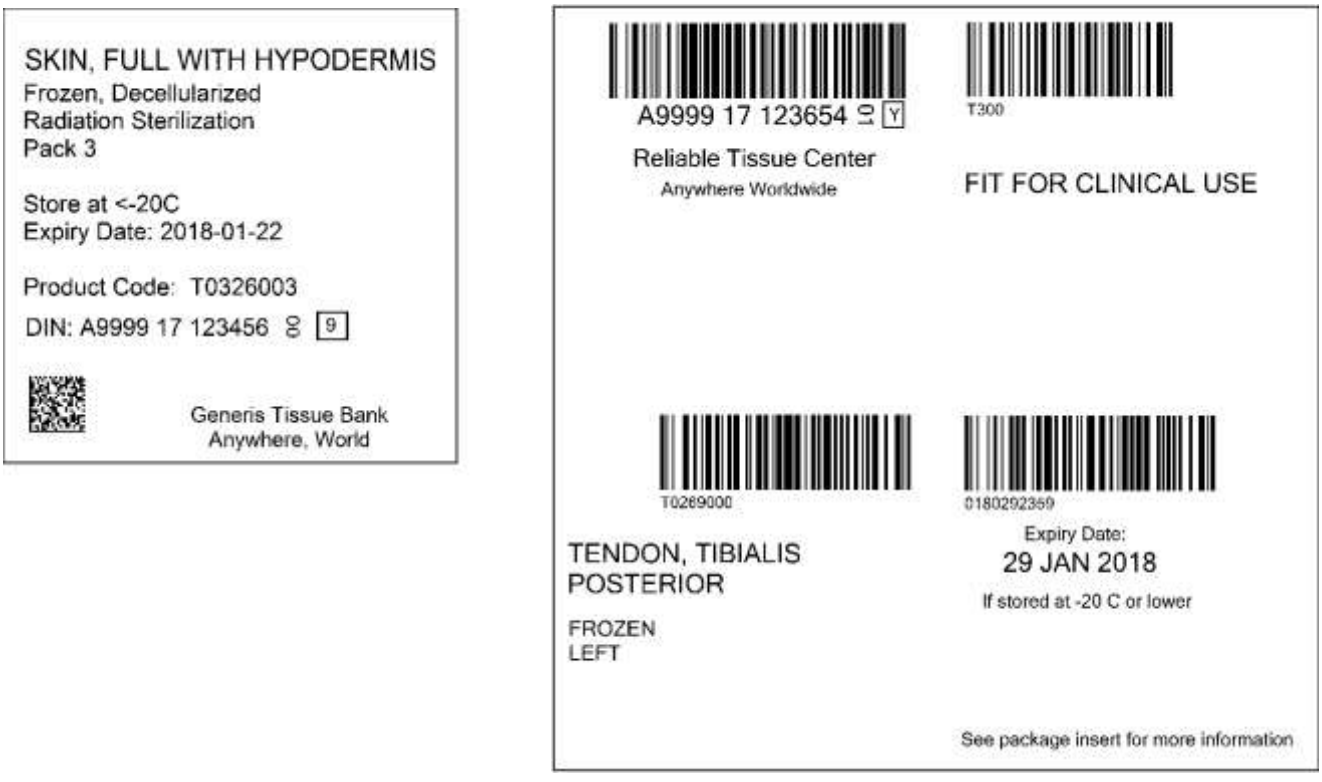


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Figure 22 Ocular Tissue Example Labels

Figure 23 Human Milk Example Labels

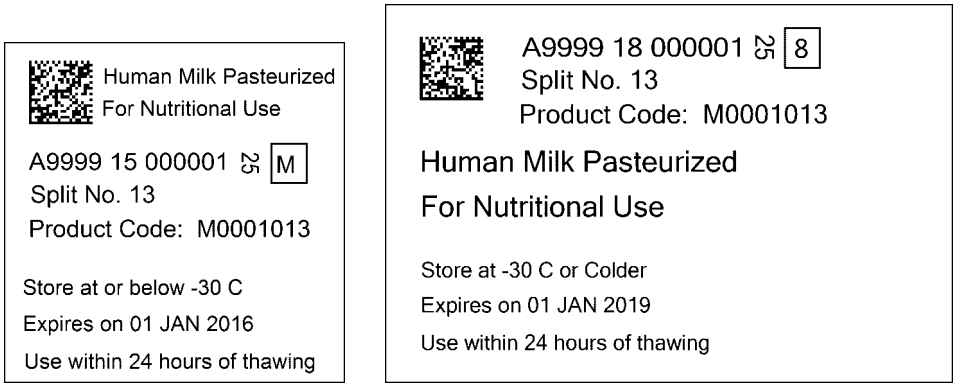

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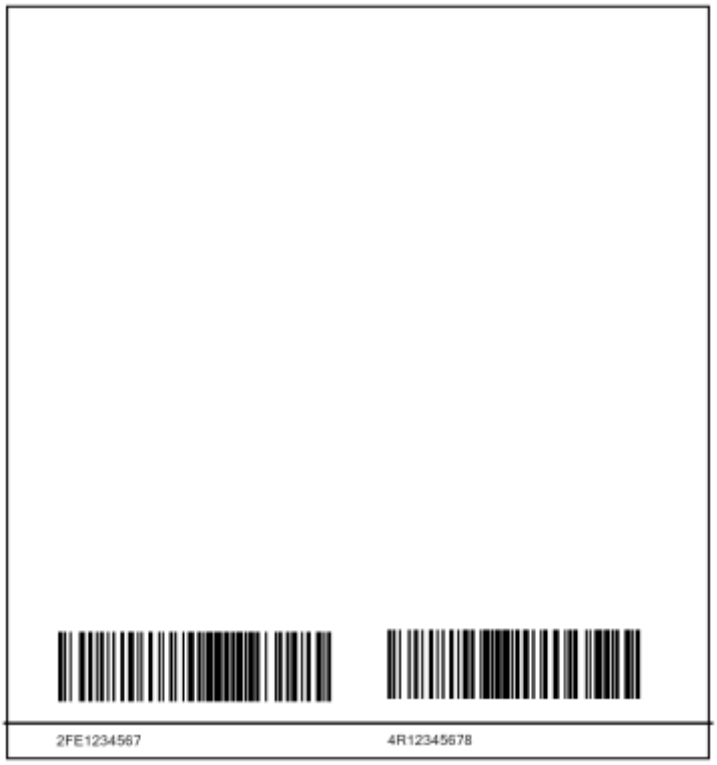
Figure 24 Example Base Label



This example represents the minimum amount of ISBT 128 information that shall appear on the base 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)

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Figure 25 Example Small Base Label

This example represents the minimum amount of ISBT 128 information that shall appear on the base 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)

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Appendix D Cross-Reference for Table Numbers

Table 37 Cross-Reference for Table Numbers [RT036]

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website*)***
RT001	Table 1	Code 128 Subset B Characters Available for Use as the Second Character of ISBT 128 Data Identifiers [RT001]
RT002	Table 30	Keyboard Entry Check Character Requirements for ISBT 128 Data Structures Utilizing Code 128 [RT002]
RT003	Table 2	
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 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 Collection in 6th Position of Product Code [RT008]
RT009	Table 9	Data Structure 012: Special Testing: Red Blood Cell Antigens — General [RT009]
RT010	Table 10	Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish [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]

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Table 37 Cross-Reference for Table Numbers [RT036] (continued)

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website)**
RT013	Table 14	Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 through 8 [RT013]
RT014	Table 15	Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 9 through 16 [RT014]
RT015 (Retired)	Table 17	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 ICCBBA-Specified Compound Messages (previously called Structured Compound Messages) (http://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables)
RT018	ICCBBA Website	Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number, Location Code (https://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables)
RT019	Table 18	Data Structure 027: Transfusion Transmitted Infection Marker [RT019]
RT020	ISBT 128 Standard, Labeling of Blood Components (ST-005)	Positioning Bar Codes on Base Labels [RT020]
RT021	ISBT 128 Standard, Labeling of Blood Components (ST-005)	Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]
RT022	ISBT 128 Standard, Labeling of Blood Components (ST-005)	Final Label Quadrants and Bar Codes [RT022]

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Table 37 Cross-Reference for Table Numbers [RT036] (continued)

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website*)***
RT023	ISBT 128 Standard, Labeling of Blood Components (ST-005)	Required Positioning of Bar Codes on Final Labels [RT023]
RT024	ISBT 128 Standard, Labeling of Blood Components (ST-005)	Recommended Positioning of Bar Codes on Final Labels [RT024]
RT025	ISBT 128 Standard, Product Description Code Database (ST-010)	CLASS Table [RT025] in
RT026	ISBT 128 Standard, Product Description Code Database (ST-010)	ATTRIBUTE Table [RT026]
RT027	ISBT 128 Standard, Product Description Code Database (ST-010)	PRODUCT DESCRIPTION Table [RT027]
RT028	ISBT 128 Standard, Product Description Code Database (ST-010)	VERSION Table [RT028]
RT029	Table 27	Special Testing: General [RT029]
RT030	Table 29	Registered Facilities [RT030]
RT031	Table 31	Header Line [RT031]
RT032	Table 32	Data Lines [RT032]
RT033	Table 33	Footer Line [RT033]
RT034	Table 34	ICCBBA-Assigned Data Labels and Content (Version 07) [RT034]
RT035	Table 36	Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character [RT035]
RT036	Table 37	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]

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Table 37 Cross-Reference for Table Numbers [RT036] (continued)

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website*)***
RT040	Table 22	Data Structure 030: RBC Serological Results [RT040]
RT041	Table 23	Data Structure 030: Number of Tests [RT041]
RT042	Table 35	IBT0001 Coding System Reference Table [RT042]
RT043	Table 28	Version Table (Special Testing) [RT043)
RT044	Table 16	Data Structure 014: Special Testing: Platelet HLA and Platelet Specific Antigens, Position 18 [RT044]
RT045	Table 24	Data Structure 031: Time Zone [RT045]
RT046	Table 25	Data Structure 031: Type of Time [RT046]
RT047	ISBT 128 Standard, Product Description Code Database (ST-010)	Categories Table [RT047]
RT048	ISBT 128 Standard, Product Description Code Database (ST-010)	Subcategories Table [RT048]
RT049	ISBT 128 Standard, Product Description Code Database (ST-010)	Classes Table [RT049]
RT050	ISBT 128 Standard, Product Description Code Database (ST-010)	Modifiers Table [RT050]
RT051	ISBT 128 Standard, Product Description Code Database (ST-010)	Class Modifier Combinations Table [RT051]
RT052	ISBT 128 Standard, Product Description Code Database (ST-010)	Attribute Groups Table [RT052]

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Table 37 Cross-Reference for Table Numbers [RT036] (continued)

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website)**
RT053	ISBT 128 Standard, Product Description Code Database (ST-010)	Attribute Values Table [RT053]
RT054	ISBT 128 Standard, Product Description Code Database (ST-010)	Product Description Codes Table [RT054]
RT055	ISBT 128 Standard, Product Description Code Database (ST-010)	Modifier Category Map Table [RT055]
RT056	ISBT 128 Standard, Product Description Code Database (ST-010)	Product Attribute Map Table [RT056]
RT057	ISBT 128 Standard, Product Description Code Database (ST-010)	Attr Old New Map [RT057]
RT058	ICCBBA Website	Facility Type Codes Used in the Registered Facilities Database (https://www.iccbba.org/tech-library/iccbba-documents/databases-and-reference-tables/reference-tables)
RT059	ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules (ST-015)	GRID Issuing Organization Database Structure [RT059]
RT060	ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules (ST-015)	Version Table (ION Database) [RT060]

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Table 37 Cross-Reference for Table Numbers [RT036] (continued)

Reference Table Number	**Table Number in *ISBT* 128 *Standard Technical Specification* or the Name of Document in which Table Appears or Website Reference**	**Name of Table in the *ISBT* 128 *Standard Technical Specification* or other ICCBBA Document (URL if the table is found on a Website*)***
RT061	ISBT 128 Standard Global Registration Identifier for Donors: ION Database and GRID Rules (ST-015)	Character to ISO/IEC 7064 Check Values [RT061]
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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