

# ISBT 128 Standard Technical Specification

Version 3.6.0

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Telephone: +1.909.793.6516 E-mail: iccbba@iccbba.org Fax: +1.909.793.6214 Website: http://www.iccbba.org

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### **Table of Contents**

1	Introduction	8
1.1	New in This Version	8
1.2	Acknowledgement	8
1.3	ISBT 128 Standard Technical Specification Version Control	9
2	Data Identifiers	. 12
2.1	The Role of Data Identifiers in ISBT 128 Bar Codes	. 12
3	Keyboard Entry Check Character K	. 15
4	Data Structures	. 17
4.1	Data Structure Index	. 17
4.2	Description of the Data Structures	.21
4.2.1	1 Donation Identification Number (Data Structure 001)	21
4.2.2	2 Blood Groups [ABO and RhD] (Data Structure 002)	23
4.2.3	3 Product Code (Data Structure 003)	24
4.2.4	4 Expiration Date (Data Structure 004)	. 27
4.2.	5 Expiration Date and Time (Data Structure 005)	. 28
4.2.6	6 Collection Date (Data Structure 006)	. 29
4.2.7	7 Collection Date and Time (Data Structure 007)	. 30
4.2.8	3 Production Date (Data Structure 008)	31
4.2.9	Production Date and Time (Data Structure 009)	. 32
4.2.1	10 Special Testing: General (Data Structure 010)	. 33
4.2.1	11 Special Testing: Red Blood Cell Antigens (Data Structure 011)	34
4.2.1	12 Special Testing: Red Blood Cell Antigens — General (Data Structure 012)	. 35
4.2.1	13 Special Testing: Red Blood Cell Antigens — Finnish (Data Structure 013)	. 36
4.2.1	14 Special Testing: Platelet HLA and Platelet Specific Antigens (Data Structure 014)	. 37
4.2.1	15 Special Testing: HLA-A and -B Alleles (Data Structure 015)	. 38
4.2.1	16 Special Testing: HLA-DRB1 Alleles (Data Structure 016)	40
4.2.1	17 Container Manufacturer and Catalog Number (Data Structure 017)	42
4.2.1	18 Container Lot Number (Data Structure 018)	44
4.2.1	19 Donor Identification Number (Data Structure 019)	45
4.2.2	20 Staff Member Identification Number (Data Structure 020)	47
4.2.2	21 Manufacturer and Catalog Number: Items Other Than Containers (Data Structure 021)	. 48
4.2.2	22 Lot Number: Items Other Than Containers (Data Structure 022)	49
4.2.2	23 Compound Message (Data Structure 023)	. 50
4.2.2	24 Patient Date of Birth (Data Structure 024)	. 52
4.2.2	25 Patient Identification Number (Data Structure 025)	. 53
4.2.2	26 Expiration Month and Year (Data Structure 026)	. 54
4.2.2	27 Infectious Markers (Data Structure 027)	. 55
4.2.2	28 Product Consignment (Data Structure 028)	. 56
4.3	Non-ICCBBA Defined Data Structures	. 57
4.3.1	1 Data Structures Defined for National (or Regional) Use	. 57
4.3.2	2 Reserved Data Identifiers for a Nationally-Specified Donor Identification Number	. 58
4.3.3	3 Confidential Unit Exclusion Status Data Structure	. 58
5	Reference Tables	. 59
6	Delivery Mechanisms for ISBT 128 Data Structures	. 83
6.1	Possible Delivery Mechanisms	. 83
6.1.1	1 Code 128 Bar Codes	. 83
6.1.2	2 2-D Bar Codes	. 83
6.1.3	3 RSS Bar Codes	. 83

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	4 RFID Tags	84
_ 6.1.	5 EDI Messages	84
7	Printing	85
7.1	Printing ISBT 128 Data Structures as Linear Bar Codes	85
7.1.	1 General Requirements	85
7.1.	2 Nominal X Dimension	85
7.1.	3 Bar Code Quiet Zones	85
7.1.4		86
7.1.	5 Verifying the Content of an ISB1 128 Bar Code	86
7.2	Printing Text Associated with Linear Bar Codes	87
7.2.	1 Eye-Readable Text	87
7.2.	2 Keyboard Entry Check Character K	88
8	Product Labeling	89
8.1	National Labeling Guidelines	89
8.2		89
8.2.	1 General Principles	89
8.2.		89
8.3	The Base Label	90
8.3.	1 Standard Base Label	90
8.3.	2 Smaller Base Label	
8.4	The Final Label	94
8.4.	1 General Layout	94
8.4.	2 Layout for Small Containers	97
8.4.	3 Final Label Text Requirements	97
8.5	Outer Package Labeling	98
8.5.		98
8.5.	2 Items Other Than Containers	98
~		~ ~ ~
9	Data Structure Coding and Decoding: Other Information and Examples of Use	99
9 9.1	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H	99 lave
9 9.1	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided	99 lave 99
9 9.1 9.2	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided	99 lave 99 100
9 9.1 9.2 9.3	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral	99 lave 99 100 101
9 9.1 9.2 9.3 9.4	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens	99 lave 99 100 101 103
9 9.1 9.2 9.3 9.4 9.5	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles	99 lave 99 100 101 103 104
9 9.1 9.2 9.3 9.4 9.5 9.5.	Data Structure Coding and Decoding: Other Information and Examples of Use Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles Tables for Data Coding	99 lave 99 100 101 103 104 104
9 9.1 9.2 9.3 9.4 9.5 9.5. 9.5.	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li> <li>Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided</li> <li>Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided</li> <li>Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral</li> <li>Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens</li> <li>Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles</li> <li>1 Tables for Data Coding</li> <li>2 Examples of Use</li> </ul>	99 lave 99 100 101 103 104 104 104
9 9.1 9.2 9.3 9.4 9.5 9.5. 9.5. 9.5.	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li> <li>Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided</li> <li>Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided</li> <li>Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral</li> <li>Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens</li> <li>Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles</li> <li>Tables for Data Coding</li> <li>Printing the Bar Codes in the Lower Right Quadrant</li> </ul>	99 lave 99 100 101 103 104 104 104 107
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li> <li>Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided</li> <li>Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided</li> <li>Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral</li> <li>Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens</li> <li>Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles</li> <li>Tables for Data Coding</li> <li>Examples of Use</li> <li>Printing the Bar Codes in the Lower Right Quadrant</li> <li>Data Structure 019 — Donor Identification Number</li> </ul>	99 lave 99 100 101 103 104 104 104 104 107 108
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li> <li>Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H Been Divided</li> <li>Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided</li> <li>Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral</li> <li>Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens</li> <li>Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles</li> <li>Tables for Data Coding</li> <li>Examples of Use</li> <li>Printing the Bar Codes in the Lower Right Quadrant</li> <li>Data Structure 019 — Donor Identification Number</li> <li>Data Structure 023 — Compound Messages</li> </ul>	99 lave 99 100 101 103 104 104 104 104 107 108 109
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.7 9.8	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 107 108 109 110
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 107 108 109 110
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 107 108 109 111 111
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.6 9.7 9.8 10 10.1 10.2	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 107 108 109 110 111 114
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.5 10 10.1 10.2 10.3	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 104 104 109 110 111 111 114
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.6 9.7 9.8 10 10.1 10.2 10.3 11	<ul> <li>Data Structure Coding and Decoding: Other Information and Examples of Use</li></ul>	99 lave 99 100 101 103 104 104 104 104 104 104 109 110 111 111 114 115 116
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1 10.2 10.3 11 11.1	Data Structure Coding and Decoding: Other Information and Examples of Use	99 lave 99 100 101 103 104 104 104 104 107 108 109 110 111 111 114 115 116
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1 10.2 10.3 11 11.1	Data Structure Coding and Decoding: Other Information and Examples of Use	99 lave 99 100 101 103 104 104 104 104 107 110 111 111 114 115 116 117
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1 10.2 10.3 11 11.1 11.2 11.3	Data Structure Coding and Decoding: Other Information and Examples of Use         Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H         Been Divided         Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided         Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral         Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens         Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles         1 Tables for Data Coding         2 Examples of Use         3 Printing the Bar Codes in the Lower Right Quadrant         Data Structure 019 — Donor Identification Number         Data Structure 027 — Infectious Markers         Data Structure 027 — Infectious Markers         Product Description Code         Special Testing: General (Data Structure 010)         Facility Identification Number Identification Code         Bar Code Concatenation         Temporal/Spatial Constraints         Output Data String         Controlling the Concatenation Process	99 lave 99 100 101 103 104 104 104 104 107 110 111 111 115 116 116 117
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.6 9.7 9.8 10 10.1 10.2 10.3 11 11.2 11.3 11.4	Data Structure Coding and Decoding: Other Information and Examples of Use	99 lave 99 100 101 103 104 104 104 107 108 109 110 111 111 115 116 116 117 117
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1 10.2 10.3 11 11.1 11.2 11.3 11.4 11.5	Data Structure Coding and Decoding: Other Information and Examples of Use         Data Structure 003 — Product Code: Coding of Blood and Cellular Therapy Products That H         Been Divided         Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided         Data Structure 012—Special Testing: Red Blood Cell AntigensGeneral         Data Structure 014 — Special Testing: HLA and Platelet-Specific Antigens         Data Structures 015 and 016 — Special Testing: HLA-A, -B and -DRB1 Alleles         1       Tables for Data Coding         2       Examples of Use         3       Printing the Bar Codes in the Lower Right Quadrant         Data Structure 019 — Donor Identification Number       Data Structure 023 — Compound Messages         Data Structure 027 — Infectious Markers       Database Tables         Product Description Code       Special Testing: General (Data Structure 010)         Facility Identification Number Identification Code       Bar Code Concatenation         Bar Code Concatenation       Temporal/Spatial Constraints         Output Data String       Concatenation Process         Verification of Valid Concatenation       Priot Process         Verification of Valid Concatenation       Priot Process         Development Marker Second Pairs       Data Structure 010	99 lave 99 100 101 103 104 104 104 107 108 109 110 111 111 115 116 117 117 117 117
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.7 9.8 10 10.1 10.2 10.3 11 11.1 11.2 11.3 11.4 11.5 12	Data Structure Coding and Decoding: Other Information and Examples of Use	99 lave 99 100 101 103 104 104 104 104 107 108 109 110 111 111 115 116 117 117 117 117 117
9 9.1 9.2 9.3 9.4 9.5 9.5 9.5 9.5 9.5 9.5 9.5 9.8 10 10.1 10.2 10.3 11 11.1 11.2 11.3 11.4 11.5 12 12.1	Data Structure Coding and Decoding: Other Information and Examples of Use	99 lave 99 100 101 103 104 104 104 104 107 108 109 111 111 115 116 117 117 117 117 118 119 119

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12.3	Examples of Use	
12.4	Container Identification Character	
13	Role of ICCBBA	
13.1	Formation and Incorporation	
13.2	Registration and Licensing	
13.3	Code Assignment	
14	ICCBBA Publications	
14.1	ISBT 128 Standard	
14.2	Technical Bulletins	
14.3	Technical Notes	
14.4	Introductory Booklets	
14.5	References	
Acrony	/ms	
Glossa	ıry	
Append	dix A Donation Identification Number Check Character [K]	
A.1	Kevboard Entry Check Character	
A.2	Computer Programs for Calculating K Using ISO 7064	
Append	dix B ISBT 128 Standard: Numbering of Versions of Documents and Databases	
Append	dix C Label Examples	
Append	dix D Cross-Reference for Table Numbers	
Index.		

### TABLES

Table 1 Code 128 Subset B Characters Available for Use as <i>ISBT 128</i> Data Identifiers [RT001]	14
Table 2 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures [RT002]	16
Table 3 Index of Data Structures [RT003]	18
Table 4 Data Structure 001: Donation Identification Number Flag Digits, ff [RT004]	59
Table 5 Data Structure 002: Blood Groups [ABO and RhD], Including Optional Type of Donation or	
Collection Information [RT005]	60
Table 6 Data Structure 002: Special Messages [RT006]	61
Table 7 Data Structure 002: Rh, Kell, and Mi <sup>a</sup> /Mur Phenotypes [RT007]	62
Table 8 Data Structure 003: Type of Donation or Collection in 6th Position of Product Code [RT008]	63
Table 9 Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 1 Through 9 [withdra	wn] 64
Table 10 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 1 Throu 9 [RT009]	gh 66
Table 11 Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 1 Throug [RT010]	3h 9 68
Table 12 Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 17 and 18: Erythroc Antigen Specified Has Been Tested and Found Negative [withdrawn]	:yte 70
Table 13 Data Structure 012: Special Testing: Red Blood Cell Antigens — General, Positions 17 and Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT011]	18: 71
Table 14 Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 17 and 1 Erythrocyte Antigen Specified Has Been Tested for and Found Negative [RT012]	8: 72
Table 15 Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 Through 8 [RT013]	73
Table 16 Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 9 Through 16 [RT014]	€ 79
Table 17 Data Structure 015: Special Testing: HLA-A and -B Alleles, Position 17 (CMV Antibody Statu [RT015]	ıs) 76

6

ISBT 128 Standard Technical Specification Version 3.6.0

Table 18 Data Structures 017 and 021: Manufacturer Identifier Codes [RT016]         Table 10 Data Structure 022: Structured Compound Magazana [BT017]	77
Table 19 Data Structure 025. Structured Compound Messages [RT017]	19
Table 20 Data Structures 024 and 025. Patient Date of Dirth and Patient Identification Number [RT010] Table 21. Data Structure 027: Infactious Markers: Desitions 1 through 0 [DT010]	5U 04
Table 21 Data Structure 027. Intectious Markers. Positions 1 through 9 [RT019]	
Table 22 Positioning Dat Codes on the Dase Labers [RT020]	90
Table 23 Positioning Bar Codes on 50 min by 75 min Containers [RT021]	92
Table 24 Fillal Label Qualitatits and Dat Codes on Final Lobels [DT022]	90 0E
Table 25 Required Positioning of Bar Codes on Final Labels [RT025]	90
Table 26 Recommended" Positioning of Bar Codes on Final Labels [RT024]	40 40
Table 27 CLASS Table [RT025]	12
	12
Table 29 PRODUCT DESCRIPTION Table [R1027]	13
Table 30 VERSION Table [R1028]17	13
Table 31 Special Testing: General [R1029]1	14
Table 32 Registered Facilities [RT030]1	15
Table 33 Header Line [RT031]12	21
Table 34 Data Lines [RT032]12	22
Table 35 Footer Line [RT033] 12	22
Table 36 ICCBBA, Inc-Assigned Data Labels and Content (Version 04) [RT034]	23
Table 37 Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the	
Checksum Character [RT035]13	37
Table 38 Cross-Reference for Table Numbers [RT036]         14	46

### FIGURES

Figure 1 Placement and Nominal Size of Bar Codes on Base Label	91
Figure 2 Placement and Nominal Size of Bar Codes on a 50 mm by 75 mm (2" by 3") Label	93
Figure 3 Placement and Nominal Size of Bar Codes on Final Label	
Figure 4 Relative Text Size of Class, Modifier, and Attributes	
Figure 5 GS1 Outer Packaging Bar Code	
Figure 6 Lower Right Quadrant with HLA Typing Results	
Figure 7 Illustration of the Terms Eye-Readable Text, Bar Code Text, and Additional Label Te	xt 136
Figure 8 Cellular Therapy Product Label	142
Figure 9 Tissue Product Label	143
Figure 10 Blood Product Label	
Figure 11 Base Label	144
Figure 12 Small Base Label	145

7

### 1 Introduction

The *ISBT 128* Standard has been utilized in various countries for many years now. It has proven capable of achieving its purpose of conveying information about human transplantation and transfusion products accurately and unambiguously. As communication technology advances, it becomes increasingly important that *ISBT 128* was developed to be "technology independent." From its original role as a labeling standard, *ISBT 128* has been re-defined as:

"An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange."

The *ISBT 128* Standard is a dynamic standard. Changes occur continually over the years as different needs are recognized. Proposals for change follow a managed process, being carefully reviewed by experts in the field in many countries before they are incorporated into the standard. Every effort is made to ensure that all changes are backward compatible.

What does not change between versions of the *ISBT 128* Standard is the basic structure of how the information is presented. Messages, regardless of their delivery mechanism, are conveyed by means of data structures. Data structures consist of data identifiers and data content. Keyboard entry check characters, used to ensure accurate keyboard entry when scanning is not possible, are mandatory with long data structures and optional with shorter data structures. As is described in the first two chapters of this standard, data identifiers and check characters help to provide a secure form of data transfer.

### 1.1 New in This Version

This version of the *ISBT 128 Standard Technical Specification* includes the addition of permanent reference numbers for tables, in addition to the sequential table numbers that may change. These permanent reference numbers are denoted as RTxxx. Because *ISBT 128* data may be used in other messaging systems (e.g., HL7), there is a need to reference these tables in documents not published by ICCBBA. To do this, a permanent reference number was needed.

Two tables that had appeared only on the ICCBBA Website (Manufacturer Identifier Codes and Structured Compound Messages) now appear in this document.

### 1.2 Acknowledgement

Many individuals have given of their time and intellect to produce and extend this *Standard*. This simple acknowledgment of their efforts is insufficient to recognize the countless hours spent in proposing particular ideas and forging consensus. Suffice it to say that those who find this *Standard* of value in their daily tasks owe them a heartfelt expression of thanks.

### 1.3 *ISBT 128* Standard Technical Specification Version Control

	Chapter, Section or Table in Version 3.5.1	Chapter, Section or Table in Version 3.6.0	Change	Rationale
1	Tables	Tables	Gave all tables Reference (RT) numbers	To allow reference to specific tables from other documents
2	Tables 18 and above	Tables 20 and above	Renumbered	Added two tables
3	4.2.1.7	4.2.1.7	Included "other non- apheresis" collection set	To allow for use of this data structure for cellular therapy or tissue containers
4	4.2.1.7	4.2.1.7	Changed reference to Table W1 on the ICCBBA Website to Table 18 within the ISBT 128 Standard Technical Specification	Table is now maintained in this document
5	4.2.21	4.2.21	Changed reference to Table W1 on the ICCBBA Website to Table 18 within the ISBT 128 Standard Technical Specification	Table is now maintained in this document
6	4.2.23	4.2.23	Changed reference to Table W2 on the ICCBBA Website to Table 19 within the ISBT 128 Standard Technical Specification	Table is now maintained in this document
7	Chapter 5, Table 4	Chapter 5, Table 4	Changed the words "blood center" to "facility" for 20-59	To allow for use by Cellular Therapy and Tissue Facilities
8		Chapter 5, Table 18	Added table	This table will now be maintained in this document for ease of reference.

	Chapter, Section or Table in Version 3.5.1	Chapter, Section or Table in Version 3.6.0	Change	Rationale
9		Chapter 5, Table 19	Added table	This table will now be maintained in this document for ease of reference.
10	8.3.1	8.3.1	Deleted information about positioning of eye-readable text	Redundant with Section 7.2.1.2
11	8.3.2, Figure 2	8.3.2, Figure 2	Changed example of small base label to include only bar codes	Consistent with title of figure and with other figures in this section
12	8.4.1	8.4.1	Deleted information about positioning of the eye-readable text	Redundant with Section 7.2.1.3
13	8.5.1	8.5.1	Deleted the word "blood" in referring to collection sets	Allow for use by Cellular Therapy and Tissue facilities
14	10	10	Added that text files may be either comma- or tab-delimited files	Facility database us tab delimited
15	10.4		Deleted section	This table will now be maintained in this document for ease of reference.
16	10.5		Deleted section	This table will now be maintained in this document for ease of reference.
17	12.1	12.1	Reworded first paragraph to read, "Verify appropriate product code" rather than "generate appropriate product code"	More accurate for whole blood
18	12.2, Table 32	12.2, Table 34	Expanded to include non-blood containers.	Allow for use by Cellular Therapy and Tissue facilities
19	12.2, Table 32	12.2, Table 34	Added that 1 is reserved for primary collection bag	Consistency with 4.2.17

	Chapter, Section or Table in Version 3.5.1	Chapter, Section or Table in Version 3.6.0	Change	Rationale
20	12.2, Table 34	12.2, Table 36	Removed reference to W1 Table; added reference to Table 18	This table will now be maintained in this document for ease of reference.
21	12.3	12.3	Added that one of the bags may be used for more than one type a product	To clarify that a container may be suitable for more than one type of product
22	Glossary	Glossary	Added "Cellular Therapy Procedures" to definition of Container Set	Allow for use by Cellular Therapy
23	Appendix C	Appendix C	Updated label example: Cellular Therapy (moved caution statements to Upper Left Quadrant)	Create more space for product information.
24	Appendix C	Appendix C	Updated label example: Base Label: Only minimum requirements shown	Give manufacturers more flexibility in design of labels
25	Appendix C	Appendix C	Added example of small base label	Provide example of this label that includes eye- readable text

### **2** Data Identifiers

Data structures defined in this document are internationally agreed entities for encoding information relevant to transfusion medicine and transplantation. Data identifier characters are for use 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 EDI message, the data identifiers may be omitted provided that the message definition unambiguously indicates that the field contains a specific *ISBT 128* data structure.

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

The **second character of the data identifier** is a non alphanumeric ASCII character. The characters used in *ISBT 128* data identifiers are shown in Table 1, page 14, together with their ASCII values. The data identifiers are listed in Table 3, beginning on page 18.

The exception to the above system is the Donation Identification Number that has 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 is also the first character of the data content.

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. All ICCBBA documents use the US ASCII mapping shown in Table 1, page 14.

### 2.1 The Role of Data Identifiers in ISBT 128 Bar Codes

*ISBT 128* bar codes comprise two elements:

- two data identifier characters that identify which *ISBT 128* data structure is being transmitted;
- the data characters that provide the data values to be interpreted in accordance with the definition of the data structure.

In order to accurately interpret information from an *ISBT 128* bar code it is essential that application software carry out the following two steps before interpreting the data values:

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

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

The following example illustrates this.

An ISBT 128 ABO/Rh Blood Group's bar code for an A, RhD Positive unit will read as:

=%6200

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

A Special Testing (Red Blood Cell Antigens) bar code on a Group O, RhD negative unit could have the value:

=\620000000000000000000

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

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

Code 128 Value	ASCII Value	Character	Name
1	33	!	exclamation mark
2	34	"	inch, double quotation mark
3	35	#	number sign
4	36	\$	dollar sign
5	37	%	per cent sign
6	38	&	ampersand
7	39	٤	foot, single quotation mark
8	40	(	left parenthesis
9	41	)	Right parenthesis
10	42	*	asterisk
11	43	+	plus sign
12	44	,	comma
13	45	-	Dash
14	46		period
15	47	/	forward slash
26	58	:	colon
27	59	;	semicolon
28	60	<	less than
29	61	=	equal to
30	62	>	greater than
31	63	?	question mark
32	64	0	at sign
59	91	[	left square bracket
60	92	١	backward slash
61	93	]	Right square bracket
62	94	۸	circumflex, caret
63	95	_	underscore
64	96	`	dipthong
91	123	{	left brace
92	124		vertical bar
93	125	}	Right brace
94	126	~	Tilde

### **3 Keyboard Entry Check Character K**

A keyboard entry check character **K** is required with some *ISBT 128* data structures in order to verify correct manual entry of the data content. **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 37 in Appendix A.

In the case of Data Structure 001 [Donation Identification Number], the calculation is based on the Donation Identification Number only, i.e., excluding the flag characters. For an example of the calculation for the 13-character string  $\alpha$ **ppppynnnnn** of the Donation Identification Number see Appendix A.

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

For example, an HLA genomic type would be printed:

0103	0201	0702	2705	19	Κ
1001	1501	9999	9999	99	L

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

Keyboard Entry Check Characters may be used with any *ISBT 128* data structure, but are required on longer data structures (see Table 2).

### Table 2 Keyboard Entry Check Character Requirements for ISBT 128 Data Structures [RT002]

Ref	Data Structure Name	Modulo 37-2 Keyboard Entry Check Character [K]
001	Donation Identification Number	Required
002	Blood Groups [ABO and RhD]	Optional
003	Product Code	Optional
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 (withdrawn)	Required
012	Special Testing: Red Blood Cell Antigens — General	Required
013	Special Testing: Red Blood Cell Antigens — Finnish	Required
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	Required
015	Special Testing: HLA-A and –B Alleles	Required
016	Special Testing: HLA-DRB1 Alleles	Required
017	Container Manufacturer and Catalog Number	Optional
018	Container Lot Number	Optional
019	Donor Identification Number	Required
020	Staff Member Identification Number	Optional
021	Manufacturer and Catalog Number: Items Other Than Containers	Optional
022	Lot Number: Items Other Than Containers	Optional
023	Compound Message	Not applicable
024	Patient Date of Birth	Optional
025	Patient Hospital Identification Number	Optional
026	Expiration Month and Year	Optional
027	Infectious Marker	Required
028	Product Consignment	Optional

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### 4 Data Structures

To facilitate the independent recognition of *ISBT 128* data structures, however used, data identifiers have been provided as described in Chapter 2. A data identifier can be stripped from the data structure if it is used in such a manner that it is unambiguously identified in the context of its use, such as in a controlled electronic data interchange (EDI) message.

### 4.1 Data Structure Index

An index of data structures is provided in Table 3, beginning on page 18, which cross references them to their descriptions in this document.

		Fir the	st Chara Data Ide	cter of entifier	Se	cond Ch of the D Identif	aracter Jata ier		
Ref	Data Structure Name		Code 128 Value	ASCII Value		Code 128 Value	ASCII Value	Data Content	See Section
001	Donation Identification Number	=	29	61	/	Α–Ν; Ρ–Ζ	:; 1–9	αppppyynnnnnff	4.2.1
002	Blood Groups [ABO and RhD]	=	29	61	%	5	37	ggre	4.2.2
003	Product Code	=	29	61	<	28	60	αooootds	4.2.3
004	Expiration Date	=	29	61	>	30	62	суујјј	4.2.4
005	Expiration Date and Time	&	6	38	^	30	62	cyyjjjhhmm	4.2.5
006	Collection Date	=	29	61	*	10	42	суујјј	4.2.6
007	Collection Date and Time	&	6	38	*	10	42	cyyjjjhhmm	4.2.7
800	Production Date	=	29	61	}	93	125	суујјј	4.2.8
009	Production Date and Time	&	6	38	}	93	125	cyyjjjhhmm	4.2.9
010	Special Testing: General	&	6	38	(	8	40	ZZZZZ	4.2.10
011	Special Testing: Red Blood Cell Antigens <b>[withdrawn</b> ]	=	29	61	{	91	123	aaaaaaaaaaaaaaaii	4.2.11
012	Special Testing: Red Blood Cell Antigens General	=	29	61	١	60	92	aaaaaaaaaaaaaaii	4.2.12

#### Table 3 Index of Data Structures [RT003]

		First Character of the Data Identifier			Second Character of the Data Identifier				
Ref	Data Structure Name		Code 128 Value	ASCII Value		Code 128 Value	ASCII Value	Data Content	See Section
013	Special Testing: Red Blood Cell Antigens Finnish	&	6	38	١	60	92	aaaaaaaaaaaaaaaii	4.2.13
014	Special Testing: Platelet HLA and Platelet-Specific Antigens	&	6	38	{	91	123	AAAABBBBBCCCCCCCC DD	4.2.14
015	Special Testing: HLA-A and -B Alleles	=	29	61	[	59	91	EEEEFFFFGGGGHHHHL M	4.2.15
016	Special Testing: HLA-DRB1 Alleles	=	29	61	"	2	34	IIIIJJJJMMMMMMMMMM	4.2.16
017	Container Manufacturer and Catalog Number	=	29	61	)	9	41	bqqwwwwww	4.2.17
018	Container Lot Number	&	6	38	)	9	41	xxxxxxxxx	4.2.18
019	Donor Identification Number	=	29	61	;	27	59	αρρρρνννννννννννννννν	4.2.19
020	Staff Member Identification Number	=	29	61	,	7	39	αρρρρυυυυυ	4.2.20
021	Manufacturer and Catalog Number: Items Other Than Containers	=	29	61	-	13	45	NN00000000	4.2.21
022	Lot Number: Items Other Than Containers	&	6	38	-	13	45	РРРРРРРР	4.2.22
023	Compound Message	=	29	61	+	11	43	aabbb	4.2.23

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		First Character of the Data Identifier		Second Character of the Data Identifier					
Ref	Data Structure Name		Code 128 Value	ASCII Value		Code 128 Value	ASCII Value	Data Content	See Section
024	Patient Date of Birth	=	29	61	#	3	35	aayyyymmdd	4.2.24
025	Patient Identification Number	&	6	38	#	3	35	aallxxxx	4.2.25
026	Expiration Month and Year	=	29	61	]	61	93	yyyymm	4.2.26
027	Infectious Markers	&	6	38	"	2	34	nnnnnnnnnnnnnnn	4.2.27
028	Product Consignment	=	29	62	\$	4	36	appppyynnnnccdd	3.2.28
	Nationally (or regionally) assigned data structures	&	6	38		a-z		Defined nationally (or regionally)	4.3.1
	Nationally defined donor identification number	&	6	38	;	27	59	Defined nationally	4.3.2
	Nationally defined confidential unit exclusion status	&	6	38	ļ	1	33	Defined nationally	4.3.3

### 4.2 Description of the Data Structures

#### 4.2.1 Donation Identification Number (Data Structure 001)

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

Purpose: To specify a donation identification number that is a unique identification of a product donation or collection or a pooled product made anywhere in the world over a one hundred year period.

Element	Length	Туре
=	1	data identifier, first character
α	1	data identifier, second character alphanumeric {A–N; P–Z; 1–9}
рррр	4	Currently numeric {0–9} However the structure is defined to support future use of alpha characters {A–N; P–Z} in the first two positions (e.g., ABC12)
уу	2	numeric {0–9}
nnnnn	6	numeric {0–9}
ff	2	numeric {0–9}

Structure: = appppyynnnnnff

The fifteen (15)-character data content string, **αppppynnnnnnff**, is encoded and interpreted as follows:

- αpppspecifies the Facility Identification Number (FIN) and is encoded<br/>and interpreted by reference to the ICCBBA Registered Facility<br/>table published and maintained by ICCBBA in the Registered User<br/>Area of the ICCBBA Website;
- **yy** specifies the last two digits of the year in which the product was collected;

Note: In practice, this is the "nominal" year. To cut down on wastage, it is permissible to use Donation Identification Number labels for up to one month in the year before, and one month in the year after, the year shown on the label.

**nnnnn** is a serial number specifying the particular collection within the given year for the facility identified by the FIN;

Note: The combination, αppppyynnnnn, forms the Donation Identification Number (DIN). Flag characters (see below), while a part of the Donation Identification Number Data Structure, are not a part of the Donation Identification Number itself. Likewise, the keyboard entry check character (see Appendix A) is not a part of the Donation Identification Number. Both the flag characters and the keyboard entry check character are for process control and are not part of the unique identification of the product.

**ff** are "flag characters." Use of non-data flag characters "ff" must conform to national guidelines. There are three general types (Table 4 on page 59) of usage:

- Type 1: Two-digit characters used for process control and defined in Table 4 on page 59;
- Type 2: Two-digit characters used for process control, but locally defined;
- Type 3: A weighted ISO/IEC 7064 modulo 37-2 check character on the entire thirteen character DIN (see Appendix A for method of calculation). Because this check character acts on the entire data portion of the Donation Identification Number, encoding the check character in the bar code data acts as a secondary check within the bar code itself, further improving the already excellent scanning error resistance of the *ISBT 128* symbology. More importantly, it provides a data transmission check character to ensure accurate communication of the scanned bar code to the host computer.

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

For a description of one way in which flags can be used see Technical Bulletin Number 7 available on the ICCBBA Website.

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

### 4.2.2 Blood Groups [ABO and RhD] (Data Structure 002)

Purpose: To indicate the blood groups [ABO and RhD] of a product and, if required, information regarding C, c, E, e, K, <u>or</u> Miltenberger phenotypes;

*AND* optionally to display information defining the type of donation or collection;

OR to display the status of a donation or collection.

Structure: =%ggre.

Element	Length	Туре
=	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}
е	1	alphanumeric {A–Z; 0–9}

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

**gg** provides ABO and RhD blood groups and type of donation or collection information and is encoded and interpreted by reference to Table 5, page 60).

Alternatively, it may define a range of special messages as shown in Table 6, page 61.

- r if used, provides Rh, Kell, and Miltenberger phenotypes and is encoded and interpreted by reference to Table 7, page 62— a value of 0 (zero) should be used if the data structure does not contain information about these phenotypes;
- e is reserved for future use. The value of e should always be set to 0 (zero).

### 4.2.3 **Product Code (Data Structure 003)**

Purpose: To identify a product intended for human use according to the *ISBT 128* scheme of Class, Modifier, and Attribute(s) (see 10.1) and optionally to encode information about the type of donation or collection and whether or not the product has been divided.

Structure: =< $\alpha$ ooootds.

Element	Length	Туре
=	1	data identifier, first character
<	1	data identifier, second character
α	1	Alphabetic {A–D; E-Z} See below
0000	4	numeric {0–9}
		alphanumeric {A–Z; a–z; 0–9}
t	1	(Depends on value of $\alpha$ , see below)
		Alphanumeric {A–Z; 0–9}, (Depends
d	1	on value of $\alpha$ , see below)
		Alphanumeric {a-z; 0-9} (Depends on
S	1	value of $\alpha$ , see below)

The eight (8)-character data content string,  $\alpha oootds$  is encoded and interpreted as follows.

**a0000** specifies the Product Description Code and is encoded and interpreted by reference to the Product Description Code database table published and maintained by ICCBBA in the Registered User Area of the ICCBBA Website (*see* 10.1).

 $\alpha$  currently indicates the following product groups:

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

oooo can only be interpreted, when combined with  $\alpha$ , through reference to the Product Description Code database.

#### **A-D National or Local Codes**

The block of product description codes, A0000-D9999, has been reserved for use as nationally or facility defined product codes.

There will 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. Local codes should be used when a product is only produced in one or a very small number of facilities. If there is any uncertainty whether the code assigned to a product should be international or local/regional/national, the user should contact the ICCBBA office.

National agencies may elect to reserve a range of these values for national assignment. Where this is done it is 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, it is the responsibility of the facility to 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 will have to be taken in interpreting the product description from a local code as this will be specific to the supplier.

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

The encoding and interpretation of tds depends upon the value of  $\alpha$ .

If  $\alpha$  is E, F or S then:

- t specifies the type of donation and is encoded and interpreted by reference to Table 8, page 63.
- **ds** provides information as to whether the unit has been divided (*see* 9.1, page 99). If the unit has not been divided, **ds** should be set to the default value of 00 (zero, zero).
  - **d** will encode the first division. First level divisions (up to 26) of the primary collection will be encoded using capital letters.
  - **s** will encode the second division. Second level subdivisions (up to 26) will be encoded using lower-case letters.

Third level subdivisions (and beyond) are not encoded.

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

If  $\alpha$  is T, tds specifies a 3-digit number of divisions of the product. If the product has not been divided, tds should be set to 000 (zero, zero, zero).

If  $\boldsymbol{\alpha}$  is X, tds is reserved for future use and the value 000 should be used at the present time.

If  $\alpha$  is A-D, tds is not defined. If tds is set to something other than 000, it should be defined in conjunction with the national/local code assignment.

### 4.2.4 Expiration Date (Data Structure 004)

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

Structure: =>cyyjjj.

Element	Length	Туре
=	1	data identifier, first character
>	1	data identifier, second character
С	1	numeric {0–9}
уу	2	numeric {0–9}
jjj	3	numeric { 0–9}

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

- **c** is the century of the year in which the item expires;
- yy is the year within the century in which the item expires;
- jjj is the Julian day of the year on which the item expires.

### 4.2.5 Expiration Date and Time (Data Structure 005)

Purpose: To indicate the day and time when the product expires.

Structure: &>cyyjjjhhmm.

Element	Length	Туре
&	1	data identifier, first character
>	1	data identifier, second character
с	1	numeric {0–9}
уу	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**, is encoded and interpreted as follows:

- **c** is the century of the year in which the product expires;
- **yy** is the year within the century in which the product expires;
- jjj is the Julian day of the year on which the product expires;
- **hh** is the hour at which the product expires (00 to 23);
- mm is the minute at which the product expires (00 to 59).

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

### 4.2.6 Collection Date (Data Structure 006)

Purpose: To indicate the day on which the product was collected.

Structure: =\*cyyjjj.

Element	Length	Туре
=	1	data identifier, first character
*	1	data identifier, second character
С	1	numeric {0–9}
уу	2	numeric {0–9}
jjj	3	numeric { 0–9}

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

- **c** is the century of the year in which the product was collected;
- yy is the year within the century in which the product was collected;
- jjj is the Julian day of the year on which the product was collected.

### 4.2.7 Collection Date and Time (Data Structure 007)

Purpose: To indicate the date and time of collection of the product.

Structure: &\*cyyjjjhhmm.

Element	Length	Туре
&	1	data identifier, first character
*	1	data identifier, second character
С	1	numeric {0–9}
уу	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**, is encoded and interpreted as follows:

- **c** is the century of the year in which the product was collected;
- **yy** is the year within the century in which the product was collected;
- jjj is the Julian day of the year on which the product was collected;
- **hh** is the hour at which the product was collected (00 to 23);
- mm is the minute at which the product was collected (00 to 59).

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

### 4.2.8 **Production Date (Data Structure 008)**

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

Structure: =}cyyjjj.

Element	Length	Туре
=	1	data identifier, first character
}	1	data identifier, second character
с	1	numeric {0–9}
уу	2	numeric {0–9}
jjj	3	numeric { 0–9}

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

- **c** is the century of the year in which the product was produced;
- yy is the year within the century in which the product was produced;
- jjj is the Julian day of the year on which the product was produced.

#### 4.2.9 **Production Date and Time (Data Structure 009)**

Purpose: To indicate the date and time of production of the product.

Structure: &}cyyjjjhhmm

Element	Length	Туре
&	1	data identifier, first character
}	1	data identifier, second character
с	1	numeric {0–9}
уу	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**, is encoded and interpreted as follows:

- **c** is the century of the year in which the product was produced;
- yy is the year within the century in which the product was produced;
- jjj is the Julian day of the year on which the product was produced;
- **hh** is the hour at which the product was produced (00 to 23);
- mm is the minute at which the product was produced (00 to 59).

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

### 4.2.10 Special Testing: General (Data Structure 010)

Purpose: To indicate special characteristics of a product such as phenotype(s), antibody(ies) present, CMV antibody status, Hemoglobin S status, etc.

Structure: &(zzzz.

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

The five (5)-character data content string, **zzzz**, is encoded and interpreted by reference to the Special Testing database table (see 10.2, page 114) published and maintained by ICCBBA in the Registered User Area of the ICCBBA Website.

## 4.2.11 Special Testing: Red Blood Cell Antigens (Data Structure 011)

Purpose: This data structure should not be used. It has been **withdrawn** and replaced by data structures 012 and 013. It is maintained for backwards compatibility.

Structure: ={aaaaaaaaaaaaaaaaii.

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

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaaaaii**, is encoded and interpreted using Table 9, page 64 and Table 12, page 70.

Note: If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 9 and Table 12, information concerning the status of those antigens should be indicated on the label text (i.e., there is no provision for the bar code representation of this information).

## 4.2.12 Special Testing: Red Blood Cell Antigens — General (Data Structure 012)

Purpose: To provide information regarding red blood cell phenotypes, CMV antibody, IgA, and Hemoglobin S status of the product.

Structure: =\aaaaaaaaaaaaaaaaii.

Element	Length	Туре
=	1	data identifier, first character
١	1	data identifier, second character
ааааааааааааааааааааааааааааааааааааааа	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaaaaii**, is encoded and interpreted using Table 10, page 66 and Table 13, page 71.

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 1 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 (no information) or NT (not tested).

See Examples of Use in 9.3, page 101.

Note: If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 10 and Table 13, information concerning the status of those antigens should be indicated on the label text (i.e., there is no provision for the bar code representation of this information).
#### 4.2.13 Special Testing: Red Blood Cell Antigens — Finnish (Data Structure 013)

Purpose: To provide information regarding red blood cell phenotypes, CMV antibody, and IgA status of the product.

Structure: &\aaaaaaaaaaaaaaaaii.

Element	Length	Туре
&	1	data identifier, first character
١	1	data identifier, second character
ааааааааааааааааааааааааааааааааааааааа	16	numeric {0–9}
ii	2	numeric {0–9}

The eighteen (18)-character data content string, **aaaaaaaaaaaaaaaaaaaii**, is encoded and interpreted using Table 11, page 68 and Table 14, page 72.

Note: If there are Red Blood Cell Antigens that have been tested for, but that are not encoded using Table 11 and Table 14, information concerning the status of those antigens should be indicated on the label text (i.e., there is no provision for the bar code representation of this information).

#### 4.2.14 Special Testing: Platelet HLA and Platelet Specific Antigens (Data Structure 014)

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

#### Structure: &{AAAABBBBBCCCCCCCDD

Element	Length	Туре
&	1	data identifier, first character
{	1	data identifier, second character
AAAA	4	numeric {0–9}
BBBB	4	numeric {0–9}
000000000000000000000000000000000000000	8	numeric {0–9}
DD	2	numeric {0–9}

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

- **AAAA** codes for HLA-A antigens.
- **BBBB** codes for HLA-B antigens.
- **CCCCCCC** codes for platelet-specific antigens, and IgA antigen and CMV antibody status.
- **DD** is reserved for future use. A default value of 00 (zero, zero) should be used at this time.

The eighteen (18)-character data content string, AAAABBBBBCCCCCCCDD, is encoded and interpreted using Table 15, beginning on page 73 and Table 16, page 75.

See Examples of Use in 9.4, page 103.

# 4.2.15 Special Testing: HLA-A and -B Alleles (Data Structure 015)

Purpose: To provide information regarding HLA-A and - B alleles for Cellular Therapy and Tissue products. This is the first of a pair of data structures (*see* 4.2.16).

Element	Length	Туре
=	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}
НННН	4	numeric {0–9}
L	1	numeric {0–9}
М	1	numeric {0–9}

Structure: =[EEEEFFFFGGGGGHHHHLM.

- **EEEE** is the first four digits of the first of the pair of HLA-A (usually) genomically-determined alleles.
- **FFFF** is the first four digits of the second of the pair of HLA-A (usually) genomically-determined alleles.
- **GGGG** is the first four digits of the first of the pair of HLA-B (usually) genomically-determined alleles.
- **HHHH** is the first four digits of the second of the pair of HLA-B (usually) genomically-determined alleles

To conform to practice the lower value of each pair should 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.

The bar code text allele numbers are preceded by an asterisk (\*) to indicate their genomically-determined status.

00 is 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 is 0000 and the bar code text is — (a dash).

L is used for coding CMV antibody status (see Table 17, page 76).

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

This reference is the official source for the latest data regarding genomically-determined HLA alleles.

#### IMGT/HLA Database

http://www.anthonynolan.org.uk/HIG/lists/class1list.html

See Examples of Use in 9.5, page 104.

#### 4.2.16 Special Testing: HLA-DRB1 Alleles (Data Structure 016)

Purpose: To provide information regarding HLA-DRB1 alleles for Cellular Therapy and Tissue products. This is the second of a pair of data structures (see 4.2.15).

Structure: ="IIIIJJJJMMMMMMMMMM

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

- **IIII** is the first four digits of the first of the pair of HLA-DRB1 (usually) genomically-determined alleles.
- **JJJJ** is the first four digits of the second of the pair of HLA-DRB1 (usually) genomically-determined alleles.

To conform to practice the lower value of each pair should 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.

The bar code text allele numbers are preceded by an asterisk (\*) to indicate their genomically-determined status.

00 is 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 is 0000 and the bar code text is — (a dash).

MMMMMMMMM is reserved for future use. A default value of 9999999999 should be used at this time.

This reference is the official source for the latest data regarding genomicallydetermined HLA alleles.

#### IMGT/HLA Database

http://www.anthonynolan.org.uk/HIG/lists/class1list.html

See Examples of Use in 9.5, page 104.

# 4.2.17 Container Manufacturer and Catalog Number (Data Structure 017)

Purpose: To specify the manufacturer and catalog number of the container set and the identifying character(s) of the individual container(s) in the set. (See Chapter 12, page 119 for use of the Manufacturer's Data File in conjunction with this data structure).

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

#### Structure: =)bqqwwwwww.

The ten (10)-character data content string, **bqqwwwwww** is encoded and interpreted as follows:

b

is the container identification character in a container or transfer set. The value of b is set as follows:

- For whole blood and other non-apheresis collection sets, 1-9 et seq is used. 1 is reserved for the primary collection container;
- for apheresis collection sets A-Z et seq is used .
- For transfer container/sets, 0 (zero) is used. If more than one type of container is present in the transfer set, numeric characters 2-9 may also be used. (The number 1 is reserved for the primary bag of a whole blood collection set.)
- **qq** specifies the identity of the container set manufacturer and is encoded and interpreted from the Manufacturer Identifier Codes table (Table 18, page 77).
- wwwwww is the manufacturer's catalog number. This must be interpreted from information provided by the manufacturer. If the catalog number is less than seven (7) characters, it should be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 0027QzE).

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Used in conjunction with the Manufacturer's Data file (see Chapter 12, page 119), 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 such things as the number of bags in the set, the anticoagulant/preservative, and the intended nominal collection volume.

#### 4.2.18 Container Lot Number (Data Structure 018)

Purpose: To specify the manufacturer's lot number for the container set.

Structure: &)xxxxxxxxx.

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

The ten (10)-character data content string, **xxxxxxxxx**, encodes the manufacturer's lot number. If the lot number is less than ten (10) characters, it should 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 must 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).

#### 4.2.19 Donor Identification Number (Data Structure 019)

Purpose: To specify a donor identification number that is unique anywhere in the world.

Element	Length	Туре
=	1	data identifier, first character
• • •	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
рррр	4	Currently, numeric {0–9} However, the structure is defined to support future use of alpha characters {A–N; P–Z} in the first two positions (e.g., ABC12)
vvvvvvvvvvvvvvvv	16	numeric {0–9}

Structure: =;appppvvvvvvvvvvvvvvvvvvv

The twenty-one (21)-character data content string, **αρρργννννννννννννννννν**, is encoded and interpreted as follows:

αpppspecifies the Facility Identification Number (FIN) and is<br/>encoded and interpreted by reference to the ICCBBA<br/>Registered Facility table (see 10.3, page 115) published<br/>and maintained by ICCBBA in the Registered User Area of<br/>the ICCBBA Website.

**vvvvvvvvvvvv** is either a nationally- or facility- assigned donor identification number. The interpretation of the assigned number requires knowledge of how such numbers are assigned in the country specified by the FIN. If the number assigned is not sixteen (16) characters, it should be padded with zeroes at the beginning of the string (i.e., the donor identification number 395421746 would be transmitted as 000000395421746). (See 9.6, page 108 for examples). 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.

#### 4.2.19.1 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.

*Note:* There is an alternative nationally-defined data structure that may be used for a donor identification number (see 4.3.2, page 58).

# 4.2.20 Staff Member Identification Number (Data Structure 020)

Purpose: To provide a data structure that may be used for staff identification.

Structure: ='appppuuuuuu.

Element	Length	Туре
=	1	data identifier, first character
I	1	data identifier, second character
α	1	alphanumeric {A–N; P–Z; 1–9}
		Currently, numeric {0–9}
		However, the structure is defined to support future use of alpha characters $(A, N; B, Z)$ in
рррр	4	the first two positions (e.g., ABC12)
սսսսսս	6	alphanumeric {A-Z, 0–9}

The eleven (11)-character data content string, **αρρρρυμυμυμ**, is encoded and interpreted as follows:

- **αpppp** specifies the Facility Identification Number (FIN) and is encoded and interpreted by reference to the ICCBBA Registered Facility table (*see* 10.3, page 115) published and maintained by ICCBBA in the Registered User Area of the ICCBBA Website.
- **uuuuu** is a facility- assigned staff member identification number. As noted above, the number may contain alphabetic characters if desired. If the string assigned is not six (6) characters, it should be padded with zeroes at the beginning of the string (i.e., the staff member identification 395A would be transmitted as 00395A).

#### 4.2.21 Manufacturer and Catalog Number: Items Other Than Containers (Data Structure 021)

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

Structure: =-NNOOOOOOO

Element	Length	Туре
=	1	data identifier, first character
-	1	data identifier, second character
NN	2	alphanumeric {A–Z; 0–9}
00000000	8	alphanumeric {A–Z; a–z; 0–9}

The ten (10)-character data content string, **NNOOOOOOO** is encoded and interpreted as follows:

- **NN** specifies the identity of the item manufacturer and is encoded and interpreted from the Manufacturer Identifier Codes table (Table 18, beginning on page 77).
- **OOOOOOOO** is the manufacturer's catalog number. This must be interpreted from information provided by the manufacturer. If the catalog number is less than eight (8) characters, it should be padded with zeroes at the beginning of the string (i.e., the catalog number 27QzE would be transmitted as 00027QzE).

## 4.2.22 Lot Number: Items Other Than Containers (Data Structure 022)

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

Structure: &-PPPPPPPP

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

The ten (10)-character data content string, **PPPPPPPP**, encodes the manufacturer's lot number. If the lot number is less than ten (10) characters, it should 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 must 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).

#### 4.2.23 Compound Message (Data Structure 023)

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

Structure: =+aabbb

Element	Length	Туре
=	1	Data identifier first character
+	1	Data identifier second character
аа	2	Numeric {0-9}
bbb	3	Numeric {0-9}

The variable length data content string **aabbb** is encoded and interpreted as follows:

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

**bbb** is either:

- all zeros indicating this is an undefined message, i.e. only the number of data structures is identified, but not what each one is;
- a three digit number referencing an entry in an ICCBBA maintained table that defines the content of this structured compound message (see Table 19, page 79).

Rules for constructing compound messages:

- A compound message will comprise a string of *ISBT 128* data structures (excluding nationally defined structures), beginning with the Compound Message (CM) data structure (Data Structure 023);
- 2. Data structures will be combined sequentially with no intervening characters, and each will begin with its data identifier characters;
- 3. The string shall only contain ISBT 128 data structures;
- 4. The number of data structures following the CM data structure will be indicated in element aa of the CM data structure
- 5. If an ICCBBA structured compound message format is used, the reference number of the structure shall be included in element bbb of the CM data structure;

6. If the message is not defined, the CM data structure will have element bbb set to zeros, but element aa will be set as specified in rule 4.

ICCBBA structured compound messages are defined in Table 19, page 79 The reference table has been established with a small number of entries. Additional entries will be made on request to the ICCBBA office and with the approval of the Editorial Board.

See 9.7, page 109 for an example of use.

#### 4.2.24 Patient Date of Birth (Data Structure 024)

Purpose: To indicate the date of birth of the patient and the location of this occurrence of the information.

Structure: =#aayyyymmdd.

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

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

- **aa** is a location code identifying where this occurrence of the information is held. For acceptable values see Table 20, page 80.
- yyyy is the year of birth.
- mm is the month of birth.
- dd is the day of birth.

#### 4.2.25 Patient Identification Number (Data Structure 025)

Purpose: To 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	Туре			
&	1	data identifier, first character			
#	1	data identifier, second character			
аа	2	numeric {0–9}			
I	2	numeric {0–9}			
XXXX	var	alpha/numeric { A-Z, a-z, 0–9}			

The variable length data content string, **aallxx...xx**, is encoded and interpreted as follows:

- **aa** is a location code identifying where this occurrence of the information is held. For acceptable values *see* Table 20, page 80;
- II is the length of the following patient number field;
- **xx...xx** is the patient identification number, alpha numeric only, punctuation characters and spaces are not permitted;

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

#### 4.2.26 Expiration Month and Year (Data Structure 026)

Purpose: To indicate a month and year of expiration for supplies. This data structure would not be used for blood, tissue, or cellular therapy products.

Structure: =]yyyymm

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

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

yyyy is the year of expiration.

**mm** is the month of expiration.

The bar code text associated with this data structure should be printed as month — year, with the month alphabetical using a three-letter abbreviation and the year a four-digit numerical representation (e.g., NOV 2007).

#### 4.2.27 Infectious Markers (Data Structure 027)

Purpose: To provide information on the infectious disease screening status of a product.

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

Structure: &"nnnnnnnnnnnnnnnn

The 18 character data content string, **nnnnnnnnnnnnnnn**, is encoded and interpreted as follows:

#### nnnnnnnnnnnnnnnn

is a string of digits, each of which identifies the result status of a pair of markers as indicated in Table 21, page 81. Currently only values in the first eight positions have been defined and so positions 9-18 should always be set to a value of 0. For each marker there are three possible outcomes:

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

The information is specific to a particular donation and thus must 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 should 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 9.8, page 110.

#### 4.2.28 Product Consignment (Data Structure 028)

Purpose: To transfer information about product shipments.

Element	Length	Туре			
=	1	data identifier, first character			
\$	1	data identifier, second character			
α	1	alphanumeric {A–N; P–Z; 1–9}			
		Currently, numeric {0–9}			
		However, the structure is defined to			
		A-N: P-Z in the first two positions			
рррр	4	(e.g., ABC12)			
уу	2	Numeric {0-9}			
nnnnn	5	Numeric {0-9}			
СС	2	Numeric {0-9}			
dd	2	Numeric {0-9}			

Structure: =&appppyynnnnnccdd

The sixteen character data string **αpppyynnnnccdd** is encoded and interpreted as follows:

specifies the Facility Identification Number (FIN) and is αpppp encoded and interpreted by reference to the ICCBBA Registered Facility table (see 10.3, page 115) published and maintained by ICCBBA in the Registered User Area of the ICCBBA Website уу is the year is a serial number nnnnn Number of container within consignment. For dispatch СС documentation (paper or electronic), this field will be set to 00 dd Total number of containers in consignment

#### 4.3 Non-ICCBBA Defined Data Structures

#### 4.3.1 Data Structures Defined for National (or Regional) Use

Data structures that fit in the *ISBT 128* model but are not internationally defined may be desirable nationally (or regionally). To support such data structures, the data identifiers &a through &z have been reserved.

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 use.

It is important that the facility identification numbers to which the definition for the national (or regional) data structure applies is documented and that software only interprets these data structures within the context of those FIN(s).

Non-ICCBBA defined data structures are not suitable for use in Compound Messages.

Element	Length	Туре			
&	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 nationally (or regionally) defined data structures with locally- or nationally-assigned product codes (see Section 4.2.3, page 24).

Note: There are internationally defined data structures for nationally-defined Donor Identification Number (data structure 019) and Patient identification Number (data structure 025).

#### 4.3.2 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 will be "&;".

Element	Length	Туре		
&	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 3.2.19, page 45).

#### 4.3.3 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.

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

### **5** Reference Tables

 Table 4 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
12–14	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, <b>αppppyynnnnn</b> including the FIN, year and the unit serial number — value is assigned as 60 plus the modulo 37-2 checksum
97–99	Reserved for future assignment

Table 5 Data St	ructure 002: Blood Groups	[ABO and RhD], Inclu	Iding Optional 1	Type of Donation or C	Sollection 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
0	55	P2	P3	P4	P5	P7	P8	P9
A	66	A2	A3	A4	A5	A7	A8	A9
В	77	B2	B3	B4	B5	B7	B8	В9
AB	88	C2	C3	C4	C5	C7	C8	C9
para-Bombay, RhD negative	D6	D2	D3	D4	D5	D7	D8	D9
para-Bombay. RhD positive	E6	E2	E3	E4	E5	E7	E8	E9
Bombay, RhD negative	G6	G2	G3	G4	G5	G7	G8	G9
Bombay, RhD positive	H6	H2	H3	H4	H5	H7	H8	H9

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### ISBT 128 Standard Technical Specification Version 3.6.0 Table 6 Data Structure 002: Special Messages [RT006]

gg	Interpretation
A0	Group A, Pooled Rh [Pooled Products]
B0	Group B, Pooled Rh [Pooled Products]
C0	Group AB, Pooled Rh [Pooled Products]
D0	Group O, Pooled Rh [Pooled Products]
E0	Pooled ABO, Rh Positive [Pooled Products]
F0	Pooled ABO, Rh Negative [Pooled Products]
G0	Pooled ABO, Pooled Rh [Pooled Products]
H0	Pooled ABO (Rh not specified) [Pooled Products]
Ма	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
Т3	RhD not specified
T4	Autologous collection/in quarantine
T5	See outer packaging for product status
T6	Must be sterilized before release

Result	ts with Anti	-Kell:	Results with:				
Not tested	Negative	Positive	Anti-C		Anti-c	Anti-E	Anti-e
0	S	т	not tested		not tested	not tested	not tested
1	А	J	neg	gative	positive	negative	positive
2	В	К	pos	sitive	positive	negative	positive
3	С	L	pos	sitive	positive	positive	positive
4	D	М	positive		positive	positive	negative
5	E	N	neg	gative	positive	positive	positive
6	F	0	neg	gative	positive	positive	negative
7	G	Р	pos	sitive	negative	negative	positive
8	н	Q	pos	sitive	negative	positive	positive
9	I	R	pos	sitive	negative	positive	negative
х	Y	Z	negative		not tested	negative	not tested
	U		Mi <sup>a</sup> /Mur negative				
	V			Mi <sup>a</sup> /Mur positive			
W				Spe m	cial Testing ust be scan	bar code proned and inte	esent and rpreted

Table 7 Data Structure 002: Rh, Kell, and Mi<sup>a</sup>/Mur Phenotypes [RT007]

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

# ISBT 128 Standard Technical Specification Version 3.6.063Table 8 Data Structure 003: Type of Donation or Collection in 6th Position of Product<br/>Code [RT008]

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

Position	1		2		3	4	4		5	(	6	7		8	3		9
Antibody																	
Antigen	Rh	K	k	Cw	VS/V	A1	Μ	N	S	S	U	Mi <sup>a</sup> †	P1	Lu <sup>a</sup>	Kp <sup>a</sup>	Js <sup>a</sup>	Wr <sup>a</sup>
Value																	
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

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

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

Position	1	0	1	1	1	2	1	3	1	4	1	5		16
Antibody														CMV
Antigen	Le <sup>a</sup>	Le⁵	Fy <sup>a</sup>	Fy⁵	Jk <sup>a</sup>	Jk⁵	Di <sup>a</sup>	Di⁵	Do <sup>a</sup>	Do <sup>b</sup>	Co <sup>a</sup>	Co <sup>b</sup>	In <sup>a</sup>	
Value														
0	nt	nt	nt	nt	nt	nt								
1	nt	neg	nt	neg	nt	neg								
2	nt	pos	nt	pos	nt	pos								
3	neg	nt	neg	nt	neg	nt								
4	neg	neg	neg	neg	neg	neg								
5	neg	pos	neg	pos	neg	pos								
6	pos	nt	pos	nt	pos	nt								
7	pos	neg	pos	neg	pos	neg								
8	pos	pos	pos	pos	pos	pos								
9	ni	ni	ni	ni	ni	ni								

#### Table 9 (continued) Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 10 Through 16 [withdrawn]

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

Position	1	2	2		3	4	4	ę	5	(	6	7	7	8	3	ç	•
Antibody																	
Antigen Value	Rh*	К	k	Cw	Mi <sup>a</sup> †	М	N	S	S	U	P1	Lu <sup>a</sup>	Kpª	Le <sup>a</sup>	Le⁵	Fy <sup>a</sup>	Fy⁵
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

Table 10 Data Structure 012: Special	Testing: Red Blood Cell Antigens -	- General, Positions 1	Through 9 [RT009]

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 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.

Position	1	0	1	1	1	2	1	3	1	4	1	5	1	6
Antibody														СМУ
Antigen Value	Jk <sup>a</sup>	Jk⁵	Do <sup>a</sup>	Do⁵	In <sup>a</sup>	Co⁵	Di <sup>a</sup>	VS/ V	Jsª	C*	С*	E*	<b>e</b> *	
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

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

 16

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.

Position	1	2	2		3		4		5		6	7	7	8	B	9	9
Antibody																	
Antigen Value	Rh	к	k	C <sup>w</sup>	Mi <sup>a</sup> †	М	N	S	S	U	P1	Lu <sup>a</sup>	Kp <sup>a</sup>	Le <sup>a</sup>	Le⁵	Fy <sup>a</sup>	Fy⁵
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

Table 11 Data Structure 013: Special	Testing: Red Blood Cell Antige	ns — Finnish, Positions 1	Through 9 [RT010]

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

Position	1	0	1	1	1	2	1:	3	1	4	1	5		16
Antibody														CMV
Antigen Value	Jk <sup>a</sup>	Jk⁵	Do <sup>a</sup>	Do⁵	C×	Co⁵	WES <sup>a</sup>	L₩ <sup>b</sup>	UI <sup>a</sup>	Ls <sup>a</sup>	Anª	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

Table 11 (continued) Data Structure 013: Special Testing: Red Blood Cell Antigens — Finnish, Positions 10 Through 16

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

### Table 12 Data Structure 011: Special Testing: Red Blood Cell Antigens, Positions 17 and18: Erythrocyte Antigen Specified Has Been Tested and Found Negative [withdrawn]

Value	Antigen	Value	Antigen	Value	Antigen	Valu e	Antigen
00	see Note	25	Kp⁵	50	Au <sup>a</sup>	75	Anª
01	Enª	26	Кр <sup>с</sup>	51	Au <sup>b</sup>	76	Dhª
02	'N'	27	Js <sup>b</sup>	52	Fy4	77	Cr <sup>a</sup>
03	V <sup>w</sup>	28	Ul <sup>a</sup>	53	Fy5	78	IFC
04	Mur	29	K11	54	Fy6	79	Knª
05	Hut	30	K12	55	removed	80	In <sup>b</sup>
06	Hil	31	K13	56	Sdª	81	Csª
09	hr <sup>s</sup>	34	K18	59	Xgª	84	Vel
10	hr <sup>B</sup>	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At <sup>a</sup>
12	Ce	37	K23	62	Sc3	87	Jr <sup>a</sup>
13	G	38	K24	63	Jo <sup>a</sup>	88	Ok <sup>a</sup>
14	Hr₀	39	Lu <sup>b</sup>	64	Do⁵	89	reserved for future use
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	cE	41	Lu4	66	Gyª	91	reserved for future use
17	C×	42	Lu5	67	Co3	92	reserved for future use
18	E <sup>w</sup>	43	Lu6	68	LW <sup>a</sup>	93	reserved for future use
19	$D^{w}$	44	Lu7	69	LW	94	reserved for future use
20	hr <sup>H</sup>	45	Lu8	70	Kx	95	reserved for future use
21	Goª	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 <sup>a</sup>	99	default

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

# Table 13 Data Structure 012: Special Testing: Red Blood Cell Antigens — General,Positions 17 and 18: Erythrocyte Antigen Specified Has Been Tested for and Found<br/>Negative [RT011]

Value	Antigen	Value	Antigen	Value	Antigen	Value	Antigen
00	information elsewhere	25	Кр <sup>ь</sup>	50	Au <sup>a</sup>	75	An <sup>a</sup>
01	En <sup>a</sup>	26	Кр <sup>с</sup>	51	Au <sup>b</sup>	76	Dh <sup>a</sup>
02	'N'	27	Js <sup>b</sup>	52	Fy4	77	Cr <sup>a</sup>
03	V <sup>w</sup>	28	Ul <sup>a</sup>	53	Fy5	78	IFC
04	Mur*	29	K11	54	Fy6	79	Kn <sup>a</sup>
05	Hut	30	K12	55	Di <sup>b</sup>	80	In <sup>b</sup>
06	Hil	31	K13	56	Sd <sup>a</sup>	81	Cs <sup>a</sup>
07	Р	32	K14	57	Wr <sup>b</sup>	82	I
08	PP <sub>1</sub> P <sup>k</sup>	33	K17	58	Yt <sup>b</sup>	83	Er <sup>a</sup>
09	hr <sup>S</sup>	34	K18	59	Xg <sup>a</sup>	84	Vel
10	hr <sup>B</sup>	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At <sup>a</sup>
12	Ce	37	K23	62	Sc3	87	Jr <sup>a</sup>
13	G	38	K24	63	Jo <sup>a</sup>	88	Ok <sup>a</sup>
14	Hr <sub>o</sub>	39	Lu <sup>b</sup>	64	removed	89	Wr <sup>a</sup>
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	cE	41	Lu4	66	Gy <sup>a</sup>	91	reserved for future use
17	Cx	42	Lu5	67	Co3	92	reserved for future use
18	E <sup>w</sup>	43	Lu6	68	LW <sup>a</sup>	93	reserved for future use
19	$D^{w}$	44	Lu7	69	LW <sup>b</sup>	94	reserved for future use
20	hr <sup>H</sup>	45	Lu8	70	Kx	95	reserved for future use
21	Go <sup>a</sup>	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 <sup>a</sup>	99	default

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# Table 14 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	Kp⁵	50	Au <sup>a</sup>	75	Anª
01	Enª	26	Кр <sup>с</sup>	51	Au⁵	76	Dh <sup>a</sup>
02	'N'	27	Js⁵	52	Fy4	77	Cr <sup>a</sup>
03	V <sup>w</sup>	28	Ul <sup>a</sup>	53	Fy5	78	IFC
04	Mur*	29	K11	54	Fy6	79	Knª
05	Hut	30	K12	55	removed	80	In <sup>b</sup>
06	Hil	31	K13	56	Sdª	81	Csª
07	Р	32	K14	57	Wr <sup>b</sup>	82	I
08	PP₁P <sup>k</sup>	33	K17	58	Yt⁵	83	Er <sup>a</sup>
09	hr <sup>s</sup>	34	K18	59	Xgª	84	Vel
10	hr <sup>B</sup>	35	K19	60	Sc1	85	Lan
11	f	36	K22	61	Sc2	86	At <sup>a</sup>
12	Ce	37	K23	62	Sc3	87	Jr <sup>a</sup>
13	G	38	K24	63	Jo <sup>a</sup>	88	Okª
14	Hr₀	39	Lu <sup>b</sup>	64	Do <sup>b</sup>	89	Wr <sup>a</sup>
15	CE	40	Lu3	65	Hy	90	reserved for future use
16	cE	41	Lu4	66	Gyª	91	reserved for future use
17	C×	42	Lu5	67	Co3	92	reserved for future use
18	E <sup>w</sup>	43	Lu6	68	LW <sup>a</sup>	93	reserved for future use
19	$D^{w}$	44	Lu7	69	LW <sup>b</sup>	94	reserved for future use
20	hr <sup>H</sup>	45	Lu8	70	Kx	95	reserved for future use
21	Goª	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 <sup>a</sup>	99	default

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
		000	00

## Table 15 Data Structure 014: Special Testing: Platelet HLA and Platelet-Specific Antigens, Positions 1 Through 8 [RT013]

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

nt — not tested; ni — no information

#### ISBT 128 Standard Technical Specification Version 3.6.0

Position	ę	•	1	0	1	1	1	2	1	3	1	4	1	5	16	
Antibody																CMV
Antigen Value	HPA- 1a	HPA- 1b	HPA- 2a	HPA- 2b	HPA- 3a	HPA- 3b	HPA- 4a	HPA- 4b	HPA- 5a	HPA- 5b	HPA- 6a	HPA- 6b	HPA- 7a	HPA- 7b	lgA	
0	nt	nt	nt													
1	nt	neg	nt	neg												
2	nt	pos	nt	pos												
3	neg	nt	neg	nt												
4	neg	neg	neg													
5	neg	pos	neg	pos												
6	pos	nt	pos	nt												
7	pos	neg	pos	neg												
8	pos	pos	pos													
9	ni	ni	ni													

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

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

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

Value	CMV Antibody Status
0	nt
1	neg
2	pos

ID	Manufac- turer	City	State/ Pro- vince	Country	Postal Code	Website
BA	Baxter Healthcare Corp, Biotech Group	Round Lake	IL	USA	60073	www.baxter.com
вс	Blood Cell Storage, Inc.	Seattle	WA	USA	98103	www.bloodcellstorage.com
CE	Cerus Europe BV	Leusden		Nether- lands	3833 AN	www.cerus.com
СН	Chartermed	Winston- Salem	NC	USA	27103	www.chartermedical.com
CO	Caridian BCT	Lakewood	CO	USA	80215	www.caridianbct.com
DI	Dideco	Mirandola Modena		Italy	41037	www.dideco.com
FE	Fenwal, Inc.	Round Lake	IL	USA	60073	www.fenwalinc.com
FR	Fresenius HemoCare Netherlands	Emmer- Compas- cuum		Nether- lands	NL- 7880AA	www.fresenius-ag.com
GC	Green Cross Medical	Kaohsiung	Taiwan	R.O.C.		www.green- cross.com.tw/html/index_e.htm
GR	Green Cross					
HA	Haemonetics Corporation	Braintree	MA	USA	02184	www.haemonetics.com
IS	International Specialty Products	Wayne	NJ	USA	07470	www.radsure.com
JM	JMS Singapore Pte Ltd	Singapore		Singapore	569620	www.jmss.com.sg
KА	Kawasumi Laboratories, Inc.	Tokyo		Japan	180- 8555	<u>www.kawasumi.jp</u>
KN	Kansuk Labaratuari Sanayi ve Ticaret A.S.	Istanbul		Turkey	34620	www.kansuk.com
LG	Laboratories Grifols, S.A.	Barcelona		Spain	108150	www.grifols.com
MA	Maco Pharma	Mouvaux		France	59420	www.macopharma.com

Table 18	Data Structures	017 and 021	: Manufacturer	<b>Identifier Codes</b>	s [RT016]
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ID	Manufac- turer	City	State/ Pro- vince	Country	Postal Code	Website
	SA					
NI	Nissho					
NP	NPBI	Emmer- Compas- cuum		Nether- lands	NL7880 AA	www.npbi.nl
PA	Pall Corporation	Port Washington	NY	USA	11050- 4605	www.pall.com
РМ	Poly Medicure Ltd	Faridabad	Haryan a	India	121004	www.polymedicure.com
ST	Stericon	Broadview	IL	USA	60153	www.stericon.com
TE	Terumo Medical Corporation	Somerset	NJ	USA	08873	www.terumomedical.com

Note: Some of the entries may not be in current use but are retained for use in look back situations. Licensed vendors who wish to have a code assigned for use in these data structures should contact ICCBBA.

Identifier	No. of Data Structures	Content
001	02	Donation Identification Number [001];Product Code [003]
002	02	Donation Identification Number [001];Blood Group [002]
003	04	Donation Identification Number [001];Blood Group [002];Product Code [003];Expiration Date and Time [005]
004	03	Donation Identification Number [001];Product Code [003];Expiration Date and Time [005]
005	02	Container Manufacturer and Catalog Number [017]; Container Lot Number [018]
006	02	Patient Birth Date Bar Code [Data structure 024]; Patient Hospital ID Number [Data Structure 025]

Table 19	Data	Structure	023:	Structured	Compound	Messages	[RT017]
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## Table 20 Data Structures 024 and 025: Patient Date of Birth and Patient Identification Number [RT018]

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

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

Table 21	Data Structure 027:	Infectious Markers:	Positions	1 through 9 [RT019]
----------	---------------------	---------------------	-----------	---------------------

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

Position		10	1	1	1	2	1	3	1	4	1	5	1	6	1	7	1	8
Antibody																		
Antigen																		
Genome Value																		
0	na																	
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		

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

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

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

## 6 Delivery Mechanisms for *ISBT* 128 Data Structures

## 6.1 Possible Delivery Mechanisms

*ISBT 128* data structures can be delivered using a number of different technologies including Code 128 bar codes, two-dimensional (2-D) bar codes, Reduced Space Symbology (RSS) 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.

## 6.1.1 Code 128 Bar Codes

Code 128 is the only linear bar code format approved for *ISBT 128*. The code must comply with the industry standard ISO/IEC 15417: 2007(E): Information technology—Automatic identification and data capture techniques—Code 128 bar code symbology specification. Additional rules regarding Code 128 bar codes used to deliver *ISBT 128* data structures are given in Chapter 7 and in Chapter 11 which deals specifically with concatenation requirements.

## 6.1.2 2-D Bar Codes

ICCBBA recommends Data Matrix (ECC 200) as the 2-D symbology for *ISBT 128*. The ISO/IEC 16022 Information technology—International symbology specification—Data Matrix should be followed.

As large an X dimension as practical should be used, with a minimum nominal X dimension of  $0.25 \text{ mm} (0.010^{\circ})$  and a maximum nominal X dimension of 1 mm  $(0.040^{\circ})$ .

Symbols should achieve a 3.0/08/650 grade level according to the ISO 15415 print quality specification for 2-D matrix symbols.

This does not preclude the use of other symbologies. Use must comply with the appropriate industry standard. Implementers wishing to use other symbologies or novel technologies should contact ICCBBA for advice before proceeding.

## 6.1.3 RSS Bar Codes

ICCBBA has not as yet specified additional requirements for Reduced Space Symbology technologies, but these will be required in order to provide an adequate level of standardization. Implementers wishing to use these or any other novel technologies should contact ICCBBA for advice before proceeding. Use must comply with the appropriate industry standard.

## 6.1.4 RFID Tags

ICCBBA has not as yet specified additional requirements for using RFID technologies, but these will be required in order to provide an adequate level of standardization. The ISBT Working Party on Information Technology is currently evaluating issues related to the application of RFID to transfusion medicine. When available, ICCBBA will consider these recommendations for inclusion in the *ISBT 128* Standard. In the interim, implementers wishing to use these or any other novel technologies should contact ICCBBA for advice before proceeding. Use must comply with the appropriate industry standard.

## 6.1.5 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.

## 7 Printing

## 7.1 Printing ISBT 128 Data Structures as Linear Bar Codes

### 7.1.1 General Requirements

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

The Code 128 value that is used to print the first and second characters of the data identifiers, and the ASCII equivalent for the Code 128 characters, are listed in Table 1 on page 14.

## 7.1.2 Nominal X Dimension

The X dimension is the width of the narrowest bar within the bar code symbol. Whenever possible, *ISBT 128* bar codes used on a container label are to be printed using a nominal X dimension of 0.25 mm (0.010"), and in no case should they be printed at a nominal X dimension smaller than 0.17 mm (0.0066").

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

It is recommended that any use of an *ISBT 128* data structure as a printed bar code, i.e., not only on container labels, use this nominal X dimension, but this is not required.

Use of a nominal X dimension of 0.25 mm (0.010") for non-ICCBBA defined bar codes (such as national use bar codes) printed on a container label is strongly recommended.

An X dimension of 0.17 mm (0.0066") is the minimum recommended for printing test tube Donation Identification Number label bar codes for space reasons.

## 7.1.3 Bar Code Quiet Zones

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 bar code. Quiet zones should be as large as compatible with the available label space with a minimum size of ten times the nominal X dimension. Note: For bar linear codes that may be concatenated, the distance between the two bar codes must fall within the specified range (see Chapter 11).

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

## 7.1.4 Bar Code Height

*ISBT 128* linear bar codes shall be of a minimum bar height that can be reliably scanned using the available scanner technologies. This height will vary depending on the scanner technology used. *ISBT 128* specified bar codes on 100 mm x 100 mm (4" x 4") labels should be printed consistently at 10 mm (0.39"). In some instances, physical limitations make it impossible to achieve this desired standard; in these instances the height of the bar code may be reduced.

## 7.1.5 Verifying the Content of an *ISBT 128* Bar Code

All users of *ISBT 128* bar codes should have access to a system to display or print an exact representation of all characters in the bar code, including the data identifier and the modulo 103 check character, and must be able to confirm, independently of the bar code scanner used, that the modulo 103 check character is in agreement with that calculated for the data stream according to the ISO/IEC 15417:2007 standard for Code 128.

Note: It is not intended that this program be in daily or even frequent use but that it be part of the resolution of any discovered error condition.

## 7.2 Printing Text Associated with Linear Bar Codes

## 7.2.1 Eye-Readable Text

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

The following sections define the requirements for this text.

#### 7.2.1.1 Donation Identification Number [001]

The eye-readable text for a Donation Identification Number is unique in that it is the sole means of presenting the data content of the bar code, i.e., it serves the dual role of eye-readable text and bar code text. As bar code text it should be printed using a sans serif typeface, but the specific decision as to how it shall be displayed should be made by a national authority, e.g.,

#### W1234 02 123456

#### V0043 99 499999

#### 7004 203 123 456, etc

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

The flag characters "**ff**" are used to convey specific information other than the unique identification of the product and need to be distinguished from the Donation Identification Number (see 4.2.1).

When Type 1 or Type 2 flag characters are used they must be printed as either:

- Numeric Presentation: The two-digit values of flags "ff" are printed rotated 90° clockwise to make them visually different from the Donation Identification Number. An example of rotated flag digits appears in Figure 7 on page 136.
- Non-numeric Presentation: A graphical icon or other representation of the value of "**ff**", e.g., for flag "**07**" printing an icon showing a small test tube

The ISO/IEC 7064 modulo 37-2 check character is encoded in the Type 3 flag digits by adding 60 to the value of the check character resulting from applying the ISO/EIC 7064 modulo 37-2 method. Because the check character eye-readable text is already present it is recommended that the values of the Type 3 flag digits themselves (range 60–96) **not** be printed as part of the eye-readable text of the Donation Identification Number.

For the keyboard entry check character, see Chapter 3.

#### 7.2.1.2 Container Manufacturer and Catalog Number [017] and Container Lot Number [018]

This requirement applies only when these bar codes are printed on a container label. The eye-readable text shall be printed in *sans serif* type in the 6 mm (0.25") segment of the base label that will remain visible after the application of the final label. The height of this text shall not exceed 3 mm (0.12"). It shall be centered vertically within the segment (see Figure 11, page 144) and commence in line with the leftmost bar of the bar code.

#### 7.2.1.3 All Other Bar Codes

Text shall appear immediately below, but not touching, the bar code; commence in line with the leftmost bar of the bar code and should be represented in sans serif type with a maximum height of 2 mm (0.08") (see Figure 7 on page 136).

## 7.2.2 Keyboard Entry Check Character K

For printing the Keyboard Entry Check Character, see Chapter 3.

## 8 Product Labeling

## 8.1 National Labeling Guidelines

National bodies should publish guidelines for labeling which adhere to the *ISBT 128* Standard, as well as the rules set forth in the *ISBT 128 Standard, Product Code Structure and Labeling* documents (Tissues, Cellular Therapy, and Blood Components).

## 8.2 Label Design

## 8.2.1 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.

The following general principles apply to label design:

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

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

Particular font sizes and types are not specified for bar code and additional text but designers must ensure clarity of all text and use larger fonts to emphasize critical information. For Latin alphabets it is recommended that proportionally spaced sans serif fonts be used.

Dates shall be printed day — month — year. The day shall be numerical, the month alphabetical, using a three-letter abbreviation. The year shall be a four-digit numerical representation.

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

## 8.2.2 Printing Text

For definitions, please refer to definitions of text on Figure 7, page 136.

## 8.3 The Base Label

## 8.3.1 Standard Base Label

Where the container is of sufficient size, it shall carry a  $100 \pm 2 \text{ mm}$  by  $106 \pm 2 \text{ mm}$  (4" by 4.25") base label.

The base label shall carry the two manufacturer's information bar codes: the Container Manufacturer and Catalog Number [017] bar code in the lower left quadrant and the Manufacturer's Lot Number [018] bar code in the lower right quadrant. The recommended position for these bar codes on  $100 \pm 2 \text{ mm}$  by 106  $\pm 2 \text{ mm}$  (4" by 4.25") label is indicated in Table 22 and is illustrated in Figure 1 on page 91.

Bar Code	Vertical Alignment	Horizontal Alignment
Container Manufacturer	3 mm (0.10") from	Bar code right edge should
and Catalog Number	bottom of Left	be at 4 mm (0.15") from
[017]	Quadrant	right edge of Left Quadrant
	[or 9 mm (0.35") from	
	bottom of label]	
Container Lot Number	3 mm (0.10") from	Bar code left edge should
[018]	bottom of Right	be at 4 mm (0.15") from
	Quadrant [or 9 mm	left edge of Right Quadrant
	(0.35") from bottom of	
	label]	

#### Table 22 Positioning Bar Codes on the Base Labels [RT020]



#### Figure 1 Placement and Nominal Size of Bar Codes on Base Label

#### Required Bar Codes 1 - Container Manufacturer and Catalog Number 2 - Container Lot Number

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

## 8.3.2 Smaller Base Label

The size of some containers does not allow a  $100 \pm 2 \text{ mm}$  by  $106 \pm 2 \text{ mm}$  (4" by 4.25") base label. In designing such labels the principles outlined in this chapter should be applied to the extent possible.

An alternative label design may be used if the container will accommodate a 50 mm x 75 mm (2" by 3") label. This base label shall carry the two manufacturer's information bar codes. The Container Manufacturer and Catalog Number [017] bar code shall be printed vertically in the upper half of the label and the Manufacturer's Lot Number [018] shall be printed vertically in the lower half of the label. The recommended position for these bar codes is indicated in Table 23 and is illustrated in Figure 2, page 93. This places the bar codes in an ideal position for concatenation.

Eye readable text for these two bar codes shall be printed beneath the bar codes. It shall be left justified immediately below the bar code. The eye readable text should remain visible after the base label is over-labeled with the final label.

In order to accommodate the smaller size of the 50 mm x 75 mm (2" by 3") label, and allow for concatenation of the bar codes, an X dimension as small as 0.17 mm (0.0066) may be used. Users should ensure that scanners selected will be able to accommodate this X dimension.

The bar code height may also be reduced to 8 mm (0.30") in order to accommodate required text.

Bar Code	From vertical center of label	From left side of label
Container manufacturer and catalog number	The right edge of the bar code is 4 mm (0.15") above the vertical center of the label	Lower edge of the bar code is 6 mm (0.25 ") from the left side of the label
Lot number	The left edge of the bar code is 4 mm (0.15") below the vertical center of the label	The lower edge of the bar code is 6 mm (0.25") from the left side of the label

#### Table 23 Positioning Bar Codes on 50 mm by 75 mm Containers [RT021]





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

## 8.4 The Final Label

### 8.4.1 General Layout

The default size of the final label is 100 (+/-2) mm by 100 (+/-2) mm (4" by 4"). Where the container size does not support this size of label, special consideration will need to be given (see 8.4.2, page 97).

The final label may be applied as a single 100 mm x 100 mm (4" by 4") label or may be built up with smaller labels applied at different stages during the process.

The final label design is based upon the concept of four equal 50 (+/-1) mm by 50 (+/-1) mm (2" by 2") quadrants. The bar codes are to be placed in these quadrants as shown in Table 24 on page 95.

Bar codes for Data Structures 001, 002, 003 and 005 must be positioned as described in Table 25 on page 95. These recommendations place the bar codes in an ideal position for concatenation.

To assist in label design, if more than one bar code is to be placed in a quadrant, e.g., Expiration Date and Special Testing, the quadrant may be divided into 50 mm by 17 mm (2" by 0.67") thirds, and one bar code placed in each subdivision of the quadrant (see Table 26, page 95). Given the need for additional label text, some adjustment of the absolute position of bar codes other than those for Data Structures 001, 002, 003 and 005 is permissible.

Figure 3, page 96, shows final label printed according to Table 25, page 95 and Table 26, page 95.

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

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

#### Table 24 Final Label Quadrants and Bar Codes [RT022]

#### Table 25 Required Positioning of Bar Codes on Final Labels [RT023]

Bar Code	Vertical Alignment	Horizontal Alignment
Donation Identification	3 mm (0.10") from top of Upper	Bar code right edge should be
Number [001]	Left Quadrant	at 4 mm (0.15") from right edge
		of Upper Left Quadrant
Product Code [003]	3 mm (0.10") from top of Lower	Bar code right edge should be
	Left Quadrant	at 4 mm (0.15") from right edge
		of Lower Left Quadrant
ABO/RhD Blood Groups	3 mm (0.10") from top of Upper	Bar code left edge should be at
[002]	Right Quadrant	4 mm (0.15") from left edge of
		Upper Right Quadrant
Expiration Date (and Time)	3 mm (0.10") from top of Lower	Bar code left edge should be at
[005]	Right Quadrant	4 mm (0.15") from left edge of
		Lower Right Quadrant

#### Table 26 Recommended\* Positioning of Bar Codes on Final Labels [RT024]

Bar Code	Vertical Alignment	Horizontal Alignment
Collection Date (and Time) [006, 007] or Production date (and Time) [008, 009]	20 mm (0.8") from top of Upper Left Quadrant	Bar code right edge should be at 4 mm (0.15") from right edge of Upper Left Quadrant
Special Testing [one of several alternative data structures]	20 mm (0.8") from top of Lower Right Quadrant	Bar code left edge should be at 4 mm (0.15") from left edge of Lower Right Quadrant

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



Required Bar Codes

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

**Optional Bar Codes** 

- 5 Special Testing 1: General
- 6 Collection (or Production) Date and Time

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

### 8.4.2 Layout for Small Containers

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

If the design includes use of linear bar codes with an X dimension of <0.25 mm (0.010"), care should be taken to ensure that all scanners that will be used to read the label are able to do so.

## 8.4.3 Final Label Text Requirements

Product description bar code text will be left justified. Other bar code text may be centered or left justified.

The product proper name (Class) may be printed as large as space allows.

It is recommended that product description bar code text should be printed with the Modifier and Attribute(s) proportionally smaller than the Class proper name. See Figure 4 (the example uses bar code text that might appear on a blood component).

#### Figure 4 Relative Text Size of Class, Modifier, and Attributes

WASHED RED BLOOD CELLS IRRADIATED

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

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

The use of color for ABO and RhD bar code text is neither prohibited nor encouraged.

For Special Testing bar code text see the Examples of Use in Chapter 9.

## 8.5 Outer Package Labeling

### 8.5.1 Containers

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

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

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

#### Figure 5 GS1 Outer Packaging Bar Code



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

## 8.5.2 Items Other Than Containers

It is recommended that for those items other than containers labeled using data structures 021 and 022 the outer packaging should also be bar coded with the descriptors listed in Section 8.5.1.

## 9 Data Structure Coding and Decoding: Other Information and Examples of Use

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

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

#### Examples of Use

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



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

As another example, consider a 200 mL unit of CPDA-1 Red Blood Cells divided into one 150 mL subunit and one 50 mL subunit (that are denoted by ds = A0 and ds = B0, respectively). The 150 mL subunit (A0) is divided into one 50 mL subunit (denoted by ds = A0) and ds = B0, respectively.

= Aa) and two 25 mL subunits (denoted by ds = Ab and ds = Ac) such as for pediatric/neonatal use. Some blood (50 mL) remains in the A0 division.



Note that if the aliquots were produced in an open system, the first five characters (a0000) will change.

## 9.2 Data Structure 003 — Product Code: Coding of Tissue Products That Have Been Divided

For tissue products, divisions are coded in the sixth, seventh, and eighth positions (tds).

T0051000 Undivided
T0051122 Container 122 from Cancellous Bone Chip product
T0051123 Container 123 from Cancellous Bone Chip product

## 9.3 Data Structure 012—Special Testing: Red Blood Cell Antigens--General

The following is an example of the use of Data Structure 012 (Table 10).

#### Example 1:

Consider the following data content string:

#### 880000087000000

this data content string is decoded as follows:

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

#### Example 2:

#### 679999999999999999

decodes as:

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

#### Example 3:

#### 99999999999999999

decodes as:

CMV antibody negative; no other information.

#### Example 4:

#### 4868813558000000

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

C+C<sup>w</sup>+c+E+e+ K+ k+ M+N+S+s+ P1- Lu(a-) Le(a-b+) Fy(a-b+) Jk(a+b+); VS/V Mi<sup>a</sup> U Kp<sup>a</sup> Js<sup>a</sup> Di<sup>a</sup> Do<sup>a</sup> Do<sup>b</sup> Co<sup>b</sup> In<sup>a</sup> and CMV not tested. The interpretation of the two (2)-character "ii" data content string is as follows. If the "ii" string is "99," then no information is provided (the default). If a number between "01" and "98" appears, unless otherwise indicated, the antigen (or characteristic) shown next to the value in Table 13 has been tested for and found negative (except for parvovirus). If the value is "00," then further information is provided, either on the container label, or in some other manner.

For example, "55" indicates Di(b-).

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

## Phenotype provided in accompanying documentation

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

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

Examples of Use

Refer to Table 15, page 73; Table 16, page 75; and Table 17, page 76.

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 (PIA1)-negative individual when there is no HLA typing data would be coded as:

9999999399999900

An HPA-1a (PIA1)-negative individual of HLA phenotype A2, B8 would be coded as:

02990899399999900

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

999999999999999400

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

## 9.5.1 Tables for Data Coding IMGT/HLA Database

http://www.ebi.ac.uk/imgt/hla/

This reference is given because ICCBBA cannot possibly maintain tables for genomic coding in a timely manner, and it is the official source for the latest data regarding genomically-determined HLA alleles.

## 9.5.2 Examples of Use

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

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

0103 0201 0702 2705 19 1001 1501 9999 9999 99

and the bar code text would appear as:

HLA-A\*0103,0201;B\*0702,2705; DRB1\*1001,1501 CMV antibody negative

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

0100 0200 0700 2700 19 1000 1500 9999 9999 99

and the bar code text would appear as:

HLA\*01,02;B\*07,27 DRB1\*10,15 CMV antibody negative A CMV antibody negative individual with the serological HLA class I typing HLA-A2, 3; B7, 44 and the genomic typing HLA-DRB1\*0301, 1501 would be coded as

0200 0300 0700 4400 19 0301 1501 9999 9999 99

and the bar code text would appear as:

HLA-A 02,03;B 07,44 DRB1\*0301,1501 CMV antibody negative

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

0200 0300 0700 4400 19 0300 1500 9999 9999 99

and the bar code text would appear as:

HLA-A\*02,03;B\*07,44; DBB1\*03,15 CMV antibody negative

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

0101 0101 0801 0801 29 0304 0304 9999 9999 99

but the bar code text would appear as:

HLA-A\*0101;B\*0801; DRB1\*0304 CMV antibody positive

in accordance with current reporting convention.

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

#### 0301 0000 0702 0801 19 0301 1501 9999 9999 99

and the bar code text would appear as:

HLA-A\*0301, — ;B0702,0801; DRB1\*0301,1501 CMV antibody negative

## 9.5.3 Printing the Bar Codes in the Lower Right Quadrant

Because the expiration date of the product also appears in this quadrant, care should be taken in placing the two bar codes such that there is room for the bar code and label text for all three bar codes, and that the bar codes maintain the required quiet zone to facilitate accurate scanning. It is recommended that to achieve the appropriate compromise, that the bar code height for all three bar codes be reduced in height to 8 mm (0.3"); there is no reason to change the X dimension. The illustration below indicates the space occupied by the bar codes and their associate eye-readable text and the space available for bar code text using this recommendation.



#### Figure 6 Lower Right Quadrant with HLA Typing Results

Note: If these long bar codes are scanned using wands ("pens") it will require extra care to ensure that the entire symbol is traversed.
### 9.6 Data Structure 019 — Donor Identification Number

Because many facilities already use nationally-assigned identification numbers for the purpose of identifying donors, the ICCBBA Technical Advisory Groups decided to standardize on a string that would encompass the longest such number of which they were aware (15 digits). To permit the use of double density coding in subset C of Code 128, a 16-digit data content string is necessary.

Note that when the number used is less than 16 digits, it should be padded with zeros at the beginning of the actual number. If desired, software developers can routinely strip off padding and present the actual number when displaying the number on a screen or when printing it. For example:

in Denmark, a possible data content string would be

000000 080656 1665

a ten (10)-digit number with six (6) leading zeroes as padding;

in France, it might be

0 1 56 05 18 033 087 78

a fifteen (15)-digit number with a single (1) leading zero as padding.

### 9.7 Data Structure 023 — Compound Messages

Compound data structures allow multiple data structures to be combined into a single data string to facilitate use of newer technology delivery systems (see 4.2.23, page 50).

Example:

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

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

where

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

=G15170612345600 is the donation identification number data structure;

=%5100 is the blood group code data structure;

=<E0001000 is the product code data structure;

&>0060252359 is the expiration date and time data structure.

An undefined message example is:

=+03000=G15170612345600=%5100&(N0001

where

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

In this case the three following data structures are donation identification number [001], blood group code [002] and special testing (general) [010].

### 9.8 Data Structure 027 — Infectious Markers

The Infectious Markers data structure allows complex testing information to be conveyed electronically (see 4.2.27, page 55).

Example: A product has the following test results:

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

Using the Infectious Markers data structure, this would be encoded according to Table 21, page 81, as:

321415000000000000

## **10 Database Tables**

ICCBBA maintains the *ISBT 128* database tables using Microsoft Access® or Microsoft Excel® for easy reference to the tables. A second format, as separate comma- or tab- delimited files, is provided for those who wish to use a different database program or who wish to download the databases into their own systems. These database tables are kept in the Registered User Area of the ICCBBA Website and are only available to registered users who are current with their annual license fee.

### **10.1Product Description Code**

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

An *ISBT 128* product code is eight (8) characters long; the first five (5) characters encode the description of the product. A product in *ISBT 128* is defined by a unique combination of the characteristics Class, Modifier, and Attribute(s). Each such combination is given a five character Product Description Code, the first character of which identifies the product group (E, F, S, T, or X, as noted above), and the remaining four characters provide a unique sequence number. These codes are maintained in a table in the database named Product Description. The Product Description Code identifies a product by mapping, via the Product Description table, to the unique combination of Class, Modifier, and Attribute(s) characteristics, all of which are referenced in the associated database tables.

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

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

As noted above, all *ISBT 128* database tables are published in the Registered User Area of the ICCBBA Website. This file is a Microsoft Access® file and is named:

### Product Codes Database - Access 2000

Comma-delimited text files of each of the tables in the Product Description Code database (Product Codes Attribute - Text, Product Codes Class - Text, Product Codes Database – Text, and Product Codes Database Version - Text) are also provided to permit end-users to incorporate these tables into any preferred database application.

The structure of the database is described in the tables below.

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

### Table 27 CLASS Table [RT025]

### Table 28 ATTRIBUTE Table [RT026]

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

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

Table 29 PRODUCT DESCRIPTION Table [RT027]

### Table 30 VERSION Table [RT028]

Field	Field Type	Field Size	Description
Version Number	Text	50	The version number of the product database
Date	Date/Time	N/A	The date issued The format is MM/DD/YYYY

### **10.2Special Testing: General (Data Structure 010)**

This database contains the test names and codes for data conveyed in Data Structure 10. It is published in the Registered User Area of the ICCBBA Website. This file is a Microsoft Access® file and is named:

#### **Special Testing General - Access 2000**

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

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

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

#### Table 31 Special Testing: General [RT029]

114

### **10.3Facility Identification Number Identification Code**

This database contains the names and locations of all ICCBBA registered facilities. It is published in the Registered User Area of the ICCBBA Website. This file is a Microsoft Excel® file and is named:

#### **Registered Facilities – xls**

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

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

### Table 32 Registered Facilities [RT030]

## **11 Bar Code Concatenation**

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

## **11.1 Temporal/Spatial Constraints**

*ISBT 128* concatenation requires that specified temporal and/or spatial constraints are 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 must be 9 ± 4 mm (0.35" ± 0.16") when the X dimension is 0.25 mm (0.010");
- the X modulus of both bar codes should be the same; (*Note: The previous* mandatory requirement for having the same X modulus 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 modulus.)
- both bar codes must 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 should be such as to allow a single straight line scan to pass completely through both bar codes;
- the minimum scan speed is 125 mm/sec (5 in/sec).

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

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

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

### **11.2 Output Data String**

*ISBT 128* concatenation results 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 is to 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.

### **11.3 Controlling the Concatenation Process**

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

a) concatenated read required;

b) concatenated read prohibited;

c) concatenated read permitted but not required.

Enforcement of these requirements can 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 needs to 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 can 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.

## **11.4 Verification of Valid Concatenation**

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

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

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

Alternatively, the scanner can 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.

## **11.5 Commonly Concatenated Bar Code Pairs**

The following is a list of bar code pairs that are commonly concatenated. The list is not exhaustive and it must be emphasized that 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 Hospital 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).

## **12 Blood Container Manufacturers Information Data File Specification**

## **12.1 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 the appropriate product type of the blood product in each 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. Each manufacturer will provide to its customers instructions on how to access and download its data files.

Each blood container has a bar coded catalog number in the lower left quadrant of the *ISBT 128* base label. Each manufacturer will maintain on its Websites, or by other electronically obtainable means, a list of each catalog offering with a downloadable data file describing the collection set, its contents, and intended use. The data file for each catalog number will include 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)

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 volume that each container is designed to hold (optional)
- Whether it is downstream from a leukocyte reduction filter

Users may download the data file for each blood container catalog number purchased into their information system. 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 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 bags. 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.

## 12.2 Structure of the Data File

The data file structure specifies the field definitions and formats together with default values and lookup table references. The message structure for an ASCII text file is provided. A separate data file is to be created for each catalog number. The structure comprises a header line, a variable number of data lines, and a footer line. An .xml message structure is being developed.

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

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

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 04, i.e., this version of the data file)
3	-	-	Available for future use

### Table 33 Header Line [RT031]

Field	Length	Format	Comment
1	20	Alpha (20)	ICCBBA-defined Data Label (see Table 36)
2	1	Alphanumeric (1)	Set to # for information relevant to the whole set, or the container identification character from the Container Manufacturer and Catalog Number data structure (017) for information specific to all containers with this identification character in the set. Numeric container identification characters are used for whole blood and other non-apheresis collection sets. 1 is reserved for the primary collection container. Alphabetic (A-Z) container identification characters are used for apheresis sets. Transfer sets should use zero (0) for container identification. If multiple bag types are found in a transfer bag set, numeric characters 2-9 should be used.
3	variable	Alphanumeric (var)	Data content ( <i>see</i> below)

### Table 35 Footer Line [RT033]

Field	Length	Format	Comment
1	8	Alpha (8)	Fixed text "FILETERM"
2	4	Numeric (4)	Count of number of data lines in file (leading zeros)

Table 36 ICCBBA, Inc-Assigned Data Labels and Content (Version 04) [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 (	Alpha (2)	М	N/A	Set
CATALOGNUMB	Manufacturer's catalog number (seven data characters as read from Container Manufacturer and Catalog Number data structure)	Alphanumer ic (7)	Μ	N/A	Set
CATNUMBTEXT	Manufacturer's catalog number as printed in documentation	free format	Μ	N/A	Set
GS1GTIN	The GS1 Global Trade Item Number	Numeric (14)	0	N/A	Set
GS1GTINCONTENT	The number of items in the carton	Numeric (3)	0	N/A	Set
CONTAINERNUMB	Number of containers in set (field 2 = #) or number of containers with specified container identification character (field 2 = container identification character).	Numeric (2)	М	N/A	Set

Data Label	Content	Format (max length)	Required*	Default Value	Application
COLLECTIONVOL	The nominal collection volume for whole blood donations (in mL)	Numeric (3)	0	N/A	Set
CONTENT	The fluid content of the container as supplied (anticoagulant, additive, etc)	select from ICCBBA lookup table‡	D	NONE	Container
CONTENTVOL	The volume of the fluid described in the CONTENT field (in mL)	Numeric (3)	0	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†	Ν	Container
RBCCONTAINER	Indicator if this is a container suitable for the storage of red cells (liquid phase)	Y or N	D†	Ν	Container
BFYCONTAINER	Indicator if this is a container suitable for the storage of buffy coat (liquid phase)	Y or N	D†	Ν	Container
LEUKREDFILTER	Indicates whether the container is downstream of a leukocyte reduction filter	Y or N	D†	Ν	Container
NOMINALVOLUME	The volume of final product that the container is designed to hold (in mL)	Numeric (4)	0	N/A	Container

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)	0	N/A	Container
MAXVOL	The maximum amount of product the container is designed to hold (in mL)	Numeric (4)	0	N/A	Container
COMMENT	Field that is available for manufacturers to add comments; end- users are not expected to upload this information	Alpha (200)	Ο	N/A	Both

N/A = not applicable\*; Y = yes; N = no

M = mandatory; O = optional (included at manufacturer's discretion); D = default value applies if the data line is not present

† At least one of the PLTCONTAINER, PMACONTAINER, RBCCONTAINER or

BFYCONTAINER fields must be set to Y for each container type

<sup>‡</sup> This table can be found in the definitions for Core Conditions in the ICCBBA document *ISBT 128 Standard Terminology for Blood, Cellular Therapy, and Tissue Product Descriptions* in the Technical Documentation area of the ICCBBA Website.

## 12.3 Examples of Use

#### An example data file:

ICCBBAMF04	
MANUFACTURER	#YZ
CATALOGNUMB	#0XY1234
CATNUMBTXT	#XY-1234
GS1GTIN	#32005000004004
GS1GTINCONTENT	#024
CONTAINERNUMB	#03
CONTAINERNUMB	101
CONTAINERNUMB	201
CONTAINERNUMB	301
COLLECTIONVOL	#450
CONTENT	1CPDA-1
CONTENTVOL	1063
CONTENT	2SAG-M
CONTENTVOL	2100
RBCCONTAINER	1Y
PMACONTAINER	2Y
PLTCONTAINER	2Y
PLTCONTAINER	3Y
LEUKREDFILTER	1Y
FILETERM0018	

This data file describes a fictional set from Manufacturer YZ with a catalog number of XY-1234, a GTIN 3200500004004, with 24 items within the carton, for the collection of 450 mL of blood. It comprises 3 containers, one with each of the container identification characters 1, 2, and 3.

The primary container contains 63 mL CPDA-1 anticoagulant and is suitable for red cell storage but not plasma or platelet storage; container 2 contains 100 mL SAG-M additive and is suitable for plasma or platelet storage, but is not suitable for red cell; container 3 has no content (*i.e.*, is empty) and is suitable for platelet storage.

A leukocyte reduction filter is present in the set. Only the red cell bag is down steam of the filter.

#### Second example for an apheresis set:

ICCBBAMF04 MANUFACTURER #YZ CATALOGNUMB #00623HS CATNUMBTEXT #623-HS GS1GTIN #32005000005003 GS1GTINCONTENT #002 CONTAINERNUMB #04 CONTAINERNUMB A01 CONTAINERNUMB B03 PMACONTAINER AY PMACONTAINER AY PMACONTAINER BY NOMINALVOLUME A1000 NOMINALVOLUME B600 FILETERM0012	
--	--

This describes a fictional apheresis set made by Manufacturer YZ with a catalog number of 623-HS, a GTIN 3200500005003, with 2 items within the carton comprising four containers: one empty container, nominal volume 1000 mL suitable for plasma storage; three empty containers, nominal volume 600 mL, suitable for plasma storage.

#### One further apheresis set example:

ICCBBAMF04		
MANUFACTURER	#HA	
CATALOGNUMB	#00946FF	
CATNUMBTEXT	#946-FF	
CONTAINERNUMB	#04	
CONTAINERNUMB	A02	
CONTAINERNUMB	B01	
CONTAINERNUMB	C01	
PLTCONTAINER	AY	
PMACONTAINER	BY	
RBCCONTAINER	СҮ	Ľ&L
NOMINALVOLUME	A1000	
NOMINALVOLUME	B600	
NOMINALVOLUME	C600	
FILETERM0013		

This describes a fictional apheresis set made by Haemonetics with a catalog number of 946-FF comprising four containers: two empty containers, nominal volume 1000 mL suitable for platelet storage; one empty container, nominal volume 600 mL, suitable for

plasma storage; one empty container, nominal volume 600 mL, suitable for red cell storage.

## **12.4 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 need 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.

## **13 Role of 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.

## **13.2 Registration and Licensing**

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

ICCBBA assigns facility and manufacturers codes. The facility codes are published in the Registered User Area of the ICCBBA Website.

Vendor codes for manufacturers who encode their identities in Data Structure 017 or 021 are found on Table 18, page 77.

## 13.3 Code Assignment

All codes used in ICCBBA data structures, with the exception of those codes designed specifically for national or local use, are assigned by ICCBBA. Once assigned, the codes are kept in the appropriate database table. All database tables can be found in the Registered User Area of the ICCBBA Website.

## **14 ICCBBA Publications**

ICCBBA publications are maintained on the ICCBBA Website. It is the responsibility of registered and licensed establishments to ensure that they have the most recent version of all ICCBBA publications by regularly consulting the listing maintained on the ICCBBA Website.

The following listing is current as of the date on the front cover of this document.

## 14.1 ISBT 128 Standard

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

## **14.2 Technical Bulletins**

Bulletin 5: Bar Code Scanner Implementation of *ISBT 128* Concatenation.

Bulletin 7: Use of Flags in the Donation Identification Number for Process Control of Critical Points During Processing and Distribution

Bulletin 8: Specification for *ISBT 128* Data Structures to Support the Secure Bedside Matching of Patient and Transfusion/Transplant Product Identification Bulletin 9: Blood Bag Identification Using *ISBT 128* and GS1

## 14.3Technical Notes

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

### **14.4 Introductory Booklets**

ISBT 128, An Introduction

ISBT 128 for Tissue Transplantation, An Introduction

ISBT 128 for Cellular Therapy, An Introduction

ISBT 128, An Introduction to Bar Coding

130

## 14.5 References

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

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

ISO/IEC 16022:2006(E): Information technology—International symbology specification—Data Matrix

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

Note: This hyperlink provides a direct source for obtaining the referenced documents; the site has complete information about ISO publications. The following link is to the ISO "home page."

http://www.iso.org/iso/en/ISOOnline.frontpage

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

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

## Acronyms

- ANSI American National Standards Institute
- ASCII American Standard Code for Information Interchange
- DIN Donation Identification Number
- EDI Electronic Data Interchange
- FIN Facility Identification Number
- IEC International Electrotechnical Commission
- ISBT International Society of Blood Transfusion
- ISO International Organization for Standardization
- RFID Radio Frequency Identification

## Glossary

**Bar code** A symbolic representation of a data structure that also includes the symbology-specific start and stop codes. In this document the unqualified use of bar code implies the use of Code 128 symbology with its associated modulo 103 check character.

Linear bar code Single row of bars and spaces

- **2-D bar code** Two-dimensional pattern of data cells
- **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.

## CheckA character used to ensure the accuracy of data. The value is calculatedcharacterbased on an algorithm applied to the data. Examples are

- the modulo 103 check character internal to Code 128
- the ISO/IEC 7064 modulo 37-2 check character appended to eye readable text that verifies accurate keyboard entry.
- **Concatenation** A method by which the information held in two bar codes is combined in the scanner into a single string of data before being sent to the host computer. *ISBT 128* places specific rules on the operation of concatenation which ensures that the two codes are adjacent to one another, hence allowing this feature to be used in label process control. (Note: *ISBT 128* concatenation is a specific enhancement to the Code 128 Specification-see Chapter 11.)
- **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** 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 4.2.1, page 21.)
Data identifier	The first two characters in a data structure that identify the data structure. These will always be present when the data structure is used as a bar code, but may be omitted when the data structure is used in situations in which the data structure identity is unambiguously and explicitly defined. (The Donation Identification Number is an exception to this rule. See 4.2.1, page 21.)
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.
Dedicated donation	A collection arranged by the collecting facility to support a specific recipient on a frequent basis (for example, to ensure limited exposure to allogeneic products).
Designated donation	A unit collected from a donor called by the collecting facility to provide product (for example, HLA-compatible) to be used by a specific recipient (or for Cellular Therapy products, possibly a small group of recipients).
Directed donation	A unit collected from a donor who presents to the collecting facility at the request of another person intending to provide product to be used by that person.
Facility	An organization that is responsible for the collection, processing, and/or distribution of <i>ISBT 128</i> -encoded products.
Final label	Labeling as it appears on a product ready for release.
Flag character	Part of the data content of a data structure used in process control or data transmission checking. Printed in eye-readable format, but distinguished in some manner from the representation of the other data characters.
ISBT 128	An international standard for the transfer of information associated with human tissue transplantation, cellular therapy, and blood transfusion. It provides for a globally unique donation numbering system, internationally standardized product definitions, and standard data structures for bar coding and electronic data interchange.
Julian Date	A numbering 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).

Label	A self-adhesive independent entity that carries a bar code (but see "base label" on the previous page) and also provides other eye-readable information.					
Primary container	The container into which the whole blood is drawn.					
Satellite container	A container other than the primary container in a container set.					
Text	(See Figure 7, page 136)					
	Eye-readable text	The eye-readable representation of the data characters in a bar code (printed left justified immediately below the bar code, unless otherwise specified).				
	Bar code text	The interpretation of the eye-readable text (the data content of the bar code).				
	Additional label text	All other information on the label that is not associated with a bar code.				
Transfer container	A container intended for post-manufacturing connection to a container set.					

## Figure 7 Illustration of the Terms Eye-Readable Text, Bar Code Text, and Additional Label Text



## Appendix A Donation Identification Number Check Character [K]

### A.1 Keyboard Entry Check Character

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

The steps in the process are as follows:

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

## Table 37 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	А	В	С
Value	0	1	2	3	4	5	6	7	8	9	10	11	12
Character	D	Е	F	G	Н	Ι	J	К	L	М	Ν	0	Ρ
Value	13	14	15	16	17	18	19	20	21	22	23	24	25
Character	Q	R	S	Т	U	V	W	Х	Y	Ζ	*		
Value	26	27	28	29	30	31	32	33	34	35	36		

### **Example of Calculation**

Position from right (n)	2 <sup>n</sup> (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	8	8	2048
7	128	9	9	1152
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 weight	148226	
Step 4		modulo 37 (fi	4	
Step 5		subtract fr	34	
Step 6	m	odulo 37 (sec	34	
	34			
	Y			

### Donation number G1234 89 654321

# A.2 Computer Programs for Calculating K Using ISO 7064

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

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

The following PASCAL language function **ISOmod37\_2** calculates and/or validates the ISO 7064 Mod 37-2 pure check character:

```
function ISOmod37_2(DonationInfo:string; K:integer) : char;
(Calculate or validate ISO mode 37-2 pure check character)
function ISOvalue(InputString:string; l:integer) : integer;
begin {Convert ASCII character value to ISO 7064 value in range 0...36}
case InputString[I] of
'0' .. '9': ISOValue := (ord(InputString[I]) - 48);
'A' .. 'Z': ISOValue := (ord(InputString[I]) - 55);
'*': ISOValue := 36;
end:
end {function ISOvalue};
var
J,Sum,CharValue,CheckValue : integer;
const
ISOCharTable : string[37] = '0123456789ABCDEFGHIJKLMNOPQRSTUVWXYZ*';
begin
Sum := 0;
for J:= 1 to K do
begin
CharValue := ISOvalue(DonationInfo,J);
Sum := ((Sum + CharValue)^2) \mod 37;
end:
{Check character value is defined to be congruent to 1 mod 37}
CheckValue := (38 - Sum) mod 37;
ISOmod37 2 := ISOCharTable[CheckValue + 1];
end {function ISOmod 37 2};
```

The following 'C' language function **CalculateMod37\_2** also implements the *"Pure system recursive method*" documented in Section 7.1 of the ISO/IEC 7064: specification:

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

ICCBBA thanks Dr Clive Hohberger, Vice President of Technology Development at Zebra Technologies Corporation, Vernon Hills, Illinois, USA, for providing the PASCAL function ISOmod37\_2, and Mr Harold Boe, Vice President of Software Development at Seagull Scientific Systems, Inc, Bellevue, Washington, USA, for providing the C-language function CalculateISO7064Mod37\_2.

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

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

#### For documents:

ISBT 128 Standard documents will include a version control sheet

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

#### For databases:

With the exception of the ICCBBA Registered Facility database, databases will have a version control sheet that is maintained on the Website.

#### For product description code database:

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

#### For Special Testing database:

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

## **Appendix C** Label Examples

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

W0000 08 123456 S X Collection Center or Registry 2nd Line of Name City, State, Zip Code	A700 O Rh Positive
Collection Date/Time 22 JAN 2008 13:59	For Use by Intended Recipient Only
Do Not Irradiate Do Not Use Leukoreduction Filters	Related Donor, 1st or 2nd Degree SMITH, GERALD R Donor # W0001 123654987 Date of Birth: 22 JUL 1962
S1134400 DESISNATED	Expiration Date/Time :
HPC, APHERESIS	24 JAN 2008 10:55
Other Additives Present See Attached Documentation for Details	s Intended Recipient: SMITH, ROGER R MRN: 123456789
Approx mL in approx mL Citrate	Date of Birth 07 JUL 1963
Store at 1 to 10 C	Processing Laboratory Name 2nd Line of Name City, State, Zip Code

Figure 8 Cellular Therapy Product Label



### Figure 9 Tissue Product Label

### Figure 10 Blood Product Label


Figure 11 Base Label



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

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

123F5678V0	0CH222V222

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

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

## Appendix D Cross-Reference for Table Numbers

Reference Table Number	Table Number in ISBT 128 Standard	Name of Table in ISBT 128 Standard Technical Specification
	Technical	
	Specification	
RT001	Table 1	Code 128 Subset B Characters Available for Use as ISBT
		128 Data Identifiers
RT002	Table 2	Keyboard Entry Check Character Requirements for ISBT 128
		Data Structures
RT003	Table 3	Index of Data Structures
RT004	Table 4	Data Structure 001: Donation Identification Number Flag Digits, ff
RT005	Table 5	Data Structure 002: Blood Groups [ABO and RhD], Including
		Optional Type of Donation or Collection Information
RT006	Table 6	Data Structure 002: Special Messages
RT007	Table 7	Data Structure 002: Rh, Kell, and Mi <sup>a</sup> /Mur Phenotypes
RT008	Table 8	Data Structure 003: Type of Donation or Collection in 6 <sup>th</sup>
		Position of Product Code
RT009	Table 10	Data Structure 012: Special Testing: Red Blood Cell
		Antigens — General, Positions 1 Through 9
RT010	Table 11	Data Structure 013: Special Testing: Red Blood Cell
		Antigens — Finnish, Positions 1 Through 9
RT011	Table 13	Data Structure 012: Special Testing: Red Blood Cell
		Antigens — General, Positions 17 and 18: Erythrocyte
		Antigen Specified Has Been Tested for and Found Negative
RT012	Table 14	Data Structure 013: Special Testing: Red Blood Cell
		Antigens — Finnish, Positions 17 and 18: Erythrocyte
DT0 (0		Antigen Specified Has Been Tested for and Found Negative
R1013	Table 15	Data Structure 014: Special Testing: Platelet HLA and
DTALL	<b>T</b> 11 40	Platelet-Specific Antigens, Positions 1 Through 8
R1014	Table 16	Data Structure 014: Special Testing: Platelet HLA and
DTAIF	<b>T</b> 11 47	Platelet-Specific Antigens, Positions 9 Through 16
R1015	Table 17	Data Structure 015: Special Testing: HLA-A and –B Alleles, Position 17 (CMV Antibody Status)
RT016	Table 18	Data Structures 017 and 021: Manufacturer Identifier Codes
RT017	Table 19	Data Structure 023: Structured Compound Messages
RT018	Table 20	Data Structures 024 and 025: Patient Date of Birth and
		Patient Identification Number
RT018	Table 21	Data Structure 027: Infectious Markers: Positions 1 through 9
RT020	Table 22	Positioning Bar Codes on the Base Labels

Table 38	<b>Cross-Reference</b>	for Table	Numbers	[RT036]

Reference Table	Table Number in ISBT 128	Name of Table in ISBT 128 Standard Technical Specification
Number	Standard	
	Technical Specification	
DT021		Desitioning Per Codes on 50 mm by 75 mm Containers
RIUZI		Final Label Que desets and Das Que des
R1022		Final Label Quadrants and Bar Codes
RT023	Table 25	Required Positioning of Bar Codes on Final Labels
RT024	Table 26	Recommended Positioning of Bar Codes on Final Labels
RT025	Table 27	CLASS Table
RT026	Table 28	ATTRIBUTE Table
RT027	Table 29	PRODUCT DESCRIPTION Table
RT028	Table 30	VERSION Table
RT029	Table 31	Special Testing: General
RT030	Table 32	Registered Facilities
RT031	Table 33	Header Line
RT032	Table 34	Data Lines
RT033	Table 35	Footer Line
RT034	Table 36	ICCBBA, Inc-Assigned Data Labels and Content (Version 04)
RT035	Table 37	Mapping from Characters to ISO/IEC 7064 Check Values and Calculated Values to the Checksum Character
RT036	Table 38	Cross-Reference forTable Numbers
Withdrawn	Table 9	Data Structure 011: Special Testing: Red Blood Cell
		Antigens, Positions 1 Through 9
Withdrawn	Table 12	Data Structure 011: Special Testing: Red Blood Cell
		Antigens, Positions 17 and 18: Erythrocyte Antigen Specified
		Has Been Tested and Found Negative

ABO Bar code concatenation, 118 Bar code position, 95 Codes, 60 Data Structure Index, 18 Data Stucture 002, 23 Printing, 97 Special message codes, 61 Attribute Label example, 97 Product code data structure, 24 Product Description Code, 111 Bar Code Height Recommended height, 86 Bar Code Size Multiple bar codes in quadrant, 107 Small containers, 97 X dimension, 85 Base Label Bar code positioning, 90 Design, 90 Illustration of bar code positioning, 91 Small. 145 Small, Bar code positioning, 92 Small, Illustration of bar code positioning, 93 Check Character Calculation of Modulo 37,2 character, 137 Computer programs for calculating, 139 **Donation Identification Number**, 15 ISO standard, 131 Keyboard entry, 15 requirement table, 15, 16 Modulo 103 Verification of scan, 86 Type 3 flag, 22 calculation, 88 Type 3 Flag Codes, 59 Class Label example, 97 Product Code Data Structure 003, 24 Product Description Code, 111 CMV Coding for Data Structure 012, 67 Coding for Data Structure 013, 69 Special Testing General Data Structure, 33 Special Testing HLA-A and -B Alleles Data Structure (015), 39 Special Testing Platelets HLA and Platelet Specific Antigens, 37

Special Testing Red Blood Cell Antigens Data Structure 012, 35 Special Testing Red Cell Antigens Finnish (Data Structure 013), 36 Code 128, 83 ISO standard, 131 Collection Date Bar code positioning, 95 Data Structure 006, 29 Data Structure 007. 30 Data Structure Index, 18 Compound Message Data stucture 023, 50 Example of use, 109 Concatenation Controlling the process, 117 Definition, 133 Output string, 117 Technical Bulletin 5, 130 Technical Note 2, 130 Temproral and spatial constraints, 116 Verification, 117 Confidential Unit Exclusion Status, 58 Data Identifiers Background, 12 Data Structures Index, 18 Definition, 134 EDI messages, 84 Eve readable text, 87 List of available ISBT 128 data identifiers, 14 Role in ISBT 128, 12 Data Matrix. 83 Data Structures Blood Group (002), 23 Collection Date (006), 29 Collection Date and Time (007), 30 Compound Message (023), 50 Confidential Unit Exclusion Status, 58 Container Lot Number (018), 44 Container Manufacturer and Catalog Number (017), 42 Donation Identification Number (001), 21 Donor Identification Number (019), 45 Expiration Date (004), 27 Expiration Date and Time (005), 28 Expiration Month and Year, 54 For Local or Regional Use, 57 Infectious markers, 55 Lot Number Items Other Than Containers (022), 49 Manufacturer and Catalog Number

Items Other Than Containers (021), 48 Nationally-Specified Donor Identification Number, 58 Patient Date of Birth (024), 52 Patient Identification Number (025), 53 Product Code (003), 24 Production Date (008), 31 Production Date and Time (009), 32 Special Testing HLA-A and -B Alleles (015), 38 HLA-DRB1 Alleles (016), 40 Platelet HLA and Platelet Specific Antigens (014), 37 Red Blood Cell Antigens (Withdrawn) (011), 34Red Blood Cell Antigens General (012), 35 Red Blood Cell Antigens—Finnish (013), 36 Special Testing General (010), 33 Staff Member Identification Number (020), 47 Table, 18 **Database Tables** Facility Identification Number, 115 IMGT/HLA database, 39, 41, 104 Product Description Code, 111 Special Testing General, 114 Delivery Mechanisms, 83 Code 128, 83 EDI, 84 **Divided Products**, 99 Example of use Blood, 99 Cellular therapy, 99 Tissue, 100 Product code data structure Blood, 25 Cellular therapy, 25 Tissues, 25 **Donation Identification Number** Data Structure 001, 21 Example of use, 108 Printing, 87 **Donation Type** Coding in ABO/RhD data structure, 60 Coding in Product Code data structure, 63 Donor Identification Number Data structure 019, 45 Nationally-Specified, 58 Electronic Messaging, 84 **Expiration Date** Bar code positioning, 95 Concatenation, 118 Data Structure 004, 27 Data Structure 005. 28 Data Structure Index, 18

Multiple bar codes in lower right quadrant, 94 Printing, 107 Expiration Month and Year Data Structure 026, 54 Facility Identification Number Assignment, 129 Database table, 115 Donation Identification Number data structure, 21 Donor Identification Number Data Structure, 45 Publication, 129 Staff Member Identification Number (data structure 020), 47, 56 Final Label Bar code positioning, 95 General layout, 94 Illustration of bar code positioning, 96 Printing of manufacturer's information text. 88 Printing text, 97 Size, 94 Small containers, 97 Text Requirements, 97 Flag Characters Coding and interpretation, 59 Data transmission check. 22 Donation Identification data structure, 22 Modulo 37-2 check, 88 Non-numeric presentation, 87 Numeric presentation, 87 Printing, 87 Technical Bulletin 7, 22 Global Trade Number, 98 GS1, 98 HLA Cellular therapy and tissue coding Examples of Use, 104 Check Character Keyboard entry, 15, 16 Codes for Data Structure 014, 73 Data Structure (015) HLA-A and -B Alleles For Tissues and Cellular Therapy, 38 Data Structure (016) HLA-DRB1 For Tissues and Cellular Therapy, 40 Data Structure index, 19 Data Stucture 014 Platelet HLA and Platelet Specific Antigens, 37 Database for HLA-A and -B and DRB1 alleles, 39, 41 Platelets coding Examples of Use, 103 Printing, 107 **ICCBBA** Code assignment, 129

History, 129 Licensing, 129 Publications. 130 Registration, 129 Technical Notes, 130 Infectious Markers Codes for Data Structure 027, 81 Data Structure 027, 55 Example of use, 110 Kell Coding in ABO/Rh data structure, 62 Label Design, 89 Base label, 90 Base label bar cocde positioning, 90 Base label example, 91 Final Label, 94 Final label bar code positioning, 95 Final label example, 96 General principles, 89 Small Base Label Bar code positioning, 92 Small Base Label, 92 Small containers, 97 Text requirements, 97 Label Text Definitions, 135 Illustration of terms, 136 Locally Defined Data Structures, 57 Manufacturer's Information Bar code positioning on base label, 91 Base label design, 90 Blood container manufacturers information data file. 119 Container Lot Number (data structure 018), 44 Container Manufacturer and Catalog Number (data structure 017), 42 Lot Number Items Other Than Containers (data structure 022), 49 Manufacturer andd Catalog Number Items Other Than Containers (data structure 021), 48 Miltenberger Coding in ABO/Rh data structure, 62 Nationally Specified Donor Identification Number, 58 Nominal X Dimension, 85 }

Outer Package Labeling, 98 Patient Date of Birth Data structure 024. 52 Patient Identification Number Data structure 025, 53 Platelet Specific Antigens, 37 Production Date Data Structure 008, 31 Data Structure 009, 32 Publications, 130 Quiet Zones, 85 Red Cell Antigen Coding Examples of use, 101 **Red Cell Antigens** Coding for Data Structure 012, 66, 71 Red Cell Antigens -- Finnish Coding for Data Structure 013, 72 References, 130, 131 Regionally Defined Data Structures, 57 Rh Coding in ABO/Rh data structure, 62 RhD Bar code concantenation, 118 Bar code positioning, 95 Codes. 60 Data Structure 002. 23 Data Structure Index, 18 Printina, 97 Special messages, 61 Special Testing General Data Structure 010, 33 HLA-A and B Alleles Data Structure 015, 38 **HLA-DRB1** Alleles Data structure 016, 40 Platelet HLA and Platelet Specific Antigens Data structure 014, 37 Red Blood Cell Antigens--Finnish Data Structure 013, 36 Red Cell Antigens General Data Structure 012, 35 Staff Member Identification Number Data structure 020, 47 X Dimension, 83, 85