



Basics of *ISBT 128*



ISBT 128 is:

- Information standard for blood, cellular therapy, tissue and derivative products
- Internationally accepted
- Supports the open movement of products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated;
- satisfies regulatory requirements for traceability and retention of information.

ISBT 128 is not just labeling.

Key Elements

- Unique donation numbering system (global)
- Standard structures and formats for information
- International product list, definitions and codes
- Standard data structures for other key information (status information, expiry, HLA profiles etc.)
- Mechanism for development and maintenance of the standard





90003 05 217134 8 **H**

上海市血液中心

血站执业许可证：
沪卫血站字(2001)第001号

临床适应症：适用于贫血且需要补充血容量的患者。

注意事项：输注前请检查包装是否完好无损，外观是否正常；除0.9%的生理盐水外不得与任何药剂在同一输液器内输注。



Z0203000

病毒灭活冷沉淀凝血因子
原料浆预制品
容量：100mL ± 10%
保养液：ACD-B
储存条件：2-6°C
制备者：1234



8400

AB

Rh 阳性



200511221200

失效期：
2005-11-22 12:00
保存期：21天
制备时间：
2005-11-02 12:00



N0011 06 005949 **F**

BB regio Noordwest



0060791312
Afg. op 20 Mrt 2006 13:12



N02710B0

VERS BEVR AF PLASMA

GESPLITST
In Na-citraat anticoagulans
Volume ca 300 ml

Voor fractionering
Bewaren bij -25°C of lager
Zie productinformatie



5100

O

Rh - D POSITIEF



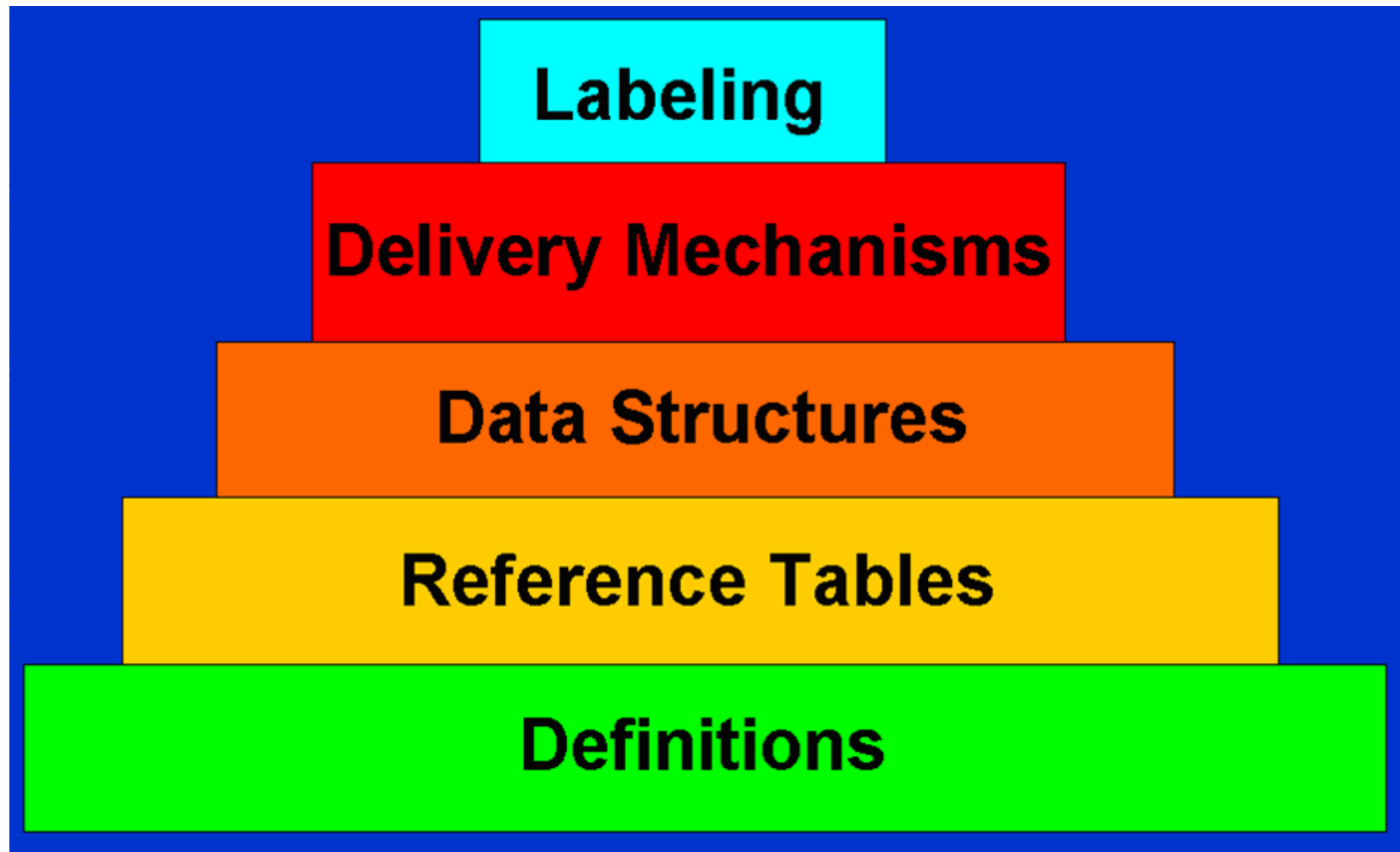
Exp.dat.

0080792359
19 Mrt 2008 23:59



N0106
anti - vaccinia aanwezig

Information Hierarchy



The Basic Elements

- Standard Definitions
 - Ensure common understanding across the community
 - Built and managed by international consensus of experts
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling

Definitions

- International consensus on appropriate terms and their definitions



The Basic Elements

- Standard Definitions
- Reference Tables
 - Provide means of mapping definitions to codes
 - Ensure consistent interpretation
 - Flexible but managed
- Data Structures
- Delivery Mechanisms
- Labeling

Reference Table

ABO and Rh(D) Blood Groups	Default: Intended Use Not Specified	Directed (Dedicated/ Designated) Collection Use Only	For Emergency Use Only	Directed (Dedicated/ Designated) Collection/ Biohazardous
O Rh(D) negative	95	91	92	93
O Rh(D) positive	51	47	48	49
A Rh(D) negative	06	02	03	04
A Rh(D) positive	62	58	59	60
B Rh(D) negative	17	13	14	15
B Rh(D) Positive	73	69	70	71
AB Rh(D) negative	28	24	25	26
AB Rh(D) positive	84	80	81	82
O	55	P2	P3	P4
A	66	A2	A3	A4
B	77	B2	B3	B4
AB	88	C2	C3	C4
para-Bombay, Rh(D) negative	D6	D2	D3	D4
para-Bombay, Rh(D) positive	E6	E2	E3	E4
Bombay, Rh(D) negative	G6	G2	G3	G4
Bombay, Rh(D) positive	H6	H2	H3	H4

Databases

PRODD ESCRIP CODE	NAM ECO DE	COMBATT RFORM	PRODESCRIP0	CODEDATE
S1122	002	@29G3	Cryopreserved HPC, MARROW NS/XX/<=-150C 10% DMSO	20 JUN 2007
S1123	006	@29G3	Cryopreserved HPC, APHERESIS NS/XX/<=-150C 10% DMSO	20 JUN 2007
S1124	010	@29G3	Cryopreserved HPC, CORD BLOOD NS/XX/<=-150C 10% DMSO	20 JUN 2007
S1125	001	@28H3	HPC, MARROW Heparin/XX/refg 3rd Party Donor:Yes	20 JUN 2007
S1130	009	@34	HPC, CORD BLOOD Citrate/XX/refg	20 JUN 2007

The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
 - Technical definitions for data transfer
 - Allow independent systems to communicate
 - Developed and maintained to meet community needs
- Delivery Mechanisms
- Labeling

Data Structure

=%O100

Data
Identifier

Data
Content

Data Identifier: Type of Information (ABO/Rh information)

Data Content: Information (Group O, Rh negative)

Each Data Structure is defined...

- In terms of its data identifiers
- In terms of its length
- In terms of the type of characters that may be present

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

Data Identifiers provide process control...

Systems should be set up to recognize data identifiers

- To ensure data is entered into the appropriate field
- To ensure a valid message length is read
- To ensure valid characters are read

Data Structures

- 001 Donation identification number
- 002 Blood group (ABO/Rh)
- 003 Product code
- 004 Expiration date
- 005 Expiration date and time
- 006 Collection date
- 007 Collection date and time

Data Structures

- 008 Production date
- 009 Production date and time
- 010 Special Testing: General
- 011 Special Testing: Red Cell Antigens
(withdrawn)
- 012 Special Testing: Red Cell Antigens--
general
- 013 Special Testing: Red Cell Antigens--
Finnish

Data Structures

- 014 Special Testing: HLA and platelet-specific antigens for Platelet Apheresis products
- 015 Special Testing: HLA-A and –B alleles for Cellular Therapy and tissue products
- 016 Special Testing: HLA-DRB1 Alleles for Cellular Therapy and tissue products

Data Structures

- 017 Container manufacturer and catalog number
- 018 Container lot number
- 019 Donor identification number
- 020 Staff member identification number

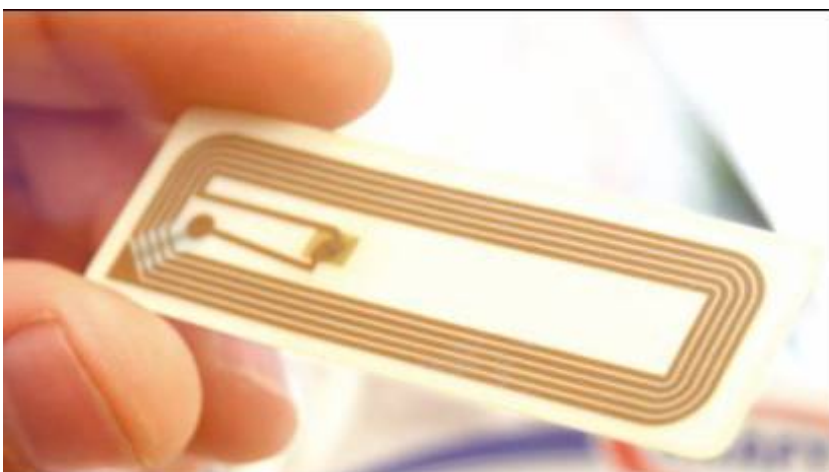
Data Structures

- 021 Manufacturer and catalog number: items other than containers
- 022 Lot number: Items other than containers
- 023 Compound message
- 024 Patient Date of Birth
- 025 Patient Identification Number

The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
 - Linear bar coding
 - 2-dimensional bar codes
 - Reduced Space Symbology (RSS) codes
 - radio frequency tags (RFID)
 - Electronic messaging
- Labeling

RFID and electronic messaging

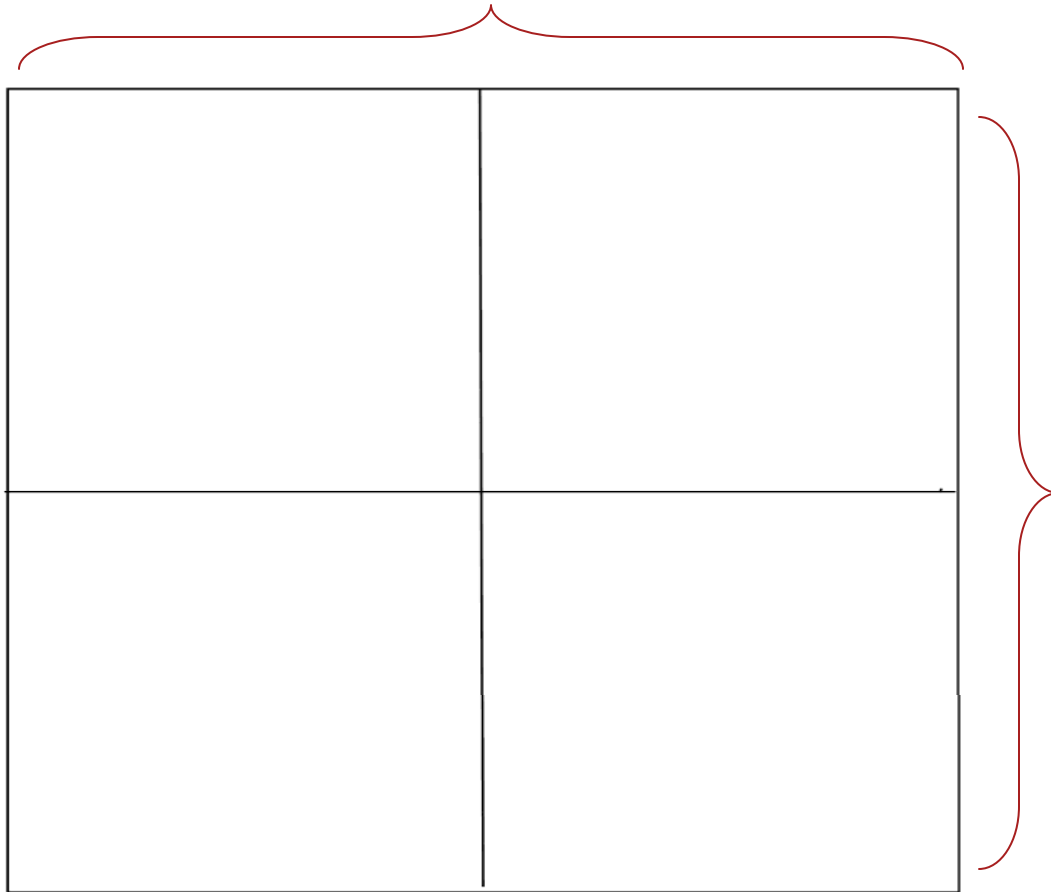


The Basic Elements

- Standard Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
 - Defines means of providing information in the right place and format
 - Ensures consistency between electronic and eye-readable information

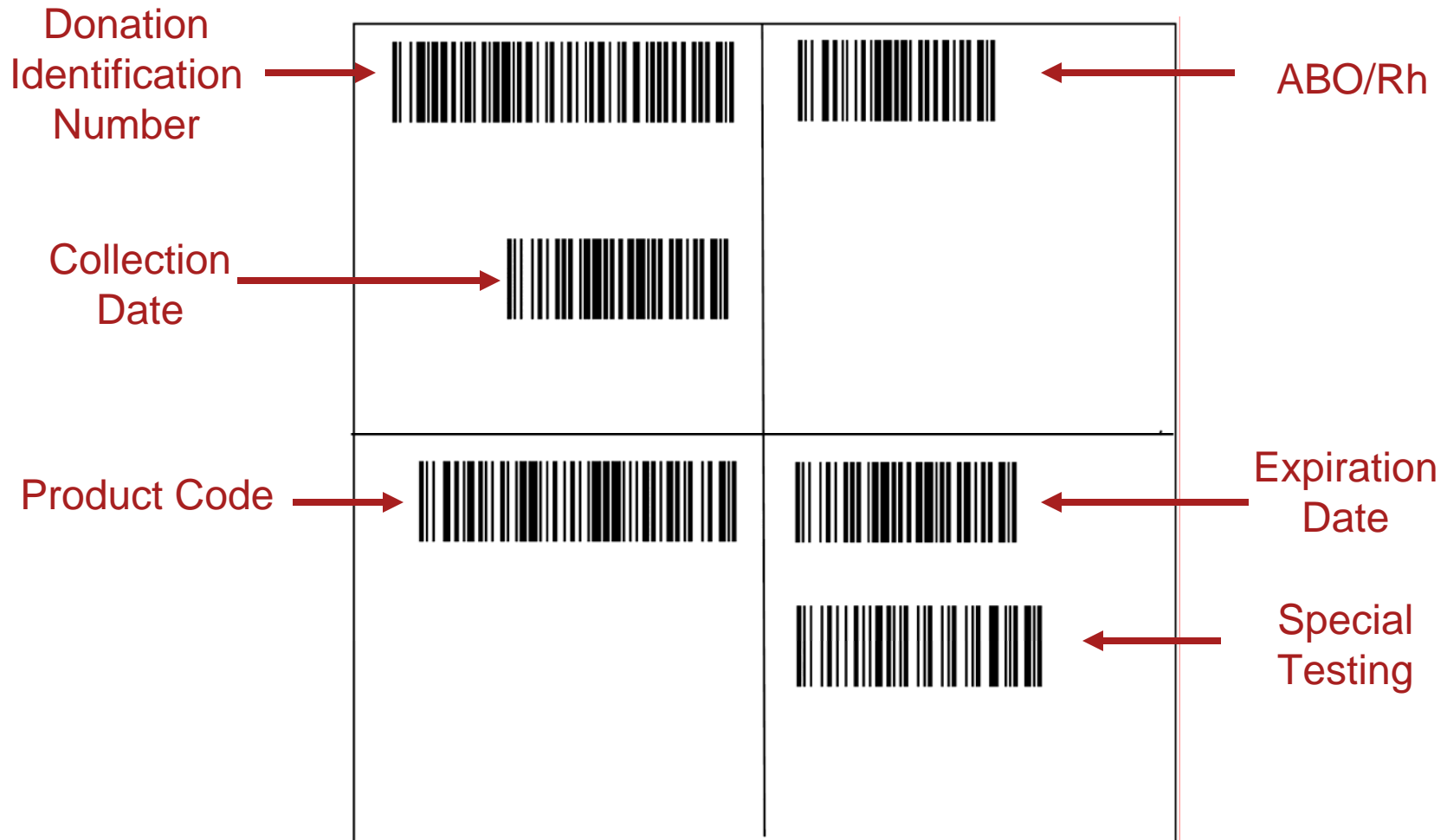
If space permits...

100 mm x 100 mm (4" x 4")



100 mm x 100 mm
(4" x 4")

Location of bar codes on 100 mm x 100 mm Label





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Other Size Labels Defined



ICCBBA



- Manages the *ISBT 128* Standard (documents, database, website)
- Non-for-profit organization
- Primary office in California
- 4 advisory groups to ensure *ISBT 128* keeps pace with new developments
- Volunteer board of directors from a variety of countries and specialties



ISBT 128

More than Identification