ISBT 128 Labelling Standard for Blood Components

Data Identifiers and Data Structures

ISBT 128 Technology Standard

- Much more than a new label layout
- Provides standard information and layout for blood component labels
- Defines data structure for information appearing on labels
- Defines technical details for the bar code
- Technical Specifications document available on ICCBBA website
ISBT 128 Data Structures

• Data structures define the way information is presented
  – Product code and unit number are just two of many standard ISBT 128 data structures
• Each data structure consists of data identifiers and data content.
• When data appears in bar code format the data content characters are printed in eye readable format immediately beneath the bar code

ISBT 128 Data Structures

• All ISBT 128 data structures have been designed with process control and future growth in mind
• Data structure can be incorporated into many information delivery systems e.g. bar codes, electronic messages, RFID tags (i.e. not restricted to Code 128 bar code symbology)
ISBT 128 Data Identifiers

- Data identifiers define the type of information the bar code contains (e.g. Product Code, ABO/Rh Blood Group)
- Each bar code on a blood product will begin with 2 data identifier characters (except Donation Number)
- The first character will always be “=” or “&”. By international agreement, these characters specify an ISBT 128 data structure
- Reduces error since data cannot be entered into an incorrect field

ISBT 128 Data Structures

- The data structures and identifiers to be used by Canadian Blood Services are summarized in this presentation
- Refer to the current version of the ISBT 128 Standard Technical Specification at ICCBBA.org for a complete description of all the ISBT 128 data structures and identifiers.
Data Identifiers for Bar Codes

- List of Data Identifiers for ISBT 128 bar codes that will appear on Canadian Blood Services labels:
  - = Donation Number
  - %= Blood Group (ABO/Rh)
  - =< Product Code
  - &* Collection Date and Time
  - &} Production Date and Time
  - &> Expiration Date & Time
  - =\ Special Testing: Red Cell Antigen
  - &( Special Testing: General

ISBT 128 Data Structures

- List of ISBT 128 Data Structures to be used by Canadian Blood Services:
  - 001 Donation Number
  - 002 Blood Groups
  - 003 Product Code
  - 005 Expiration Date and Time
  - 007 Collection Date and Time
  - 009 Production Date and Time
  - 010 Special Testing: General
  - 012 Special Testing: Red Blood Cell Antigens - General
Donation Number

ISBT 128 Data Structure 001

<table>
<thead>
<tr>
<th>Data identifier</th>
<th>=</th>
<th>ppppyynnnnff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Identification Number (including country identifier)</td>
<td>≈</td>
<td>pppp</td>
</tr>
<tr>
<td>Year of Collection</td>
<td>yy</td>
<td></td>
</tr>
<tr>
<td>Serial Number</td>
<td>nnnnnn</td>
<td></td>
</tr>
<tr>
<td>Flag Character (NOT part of Donation Number)</td>
<td>ff</td>
<td></td>
</tr>
</tbody>
</table>
ISBT 128 Donation Number

= C0500 07 123456 = Q

• 13 Digit Donation Number
  – Facility identification number (global)
  – Year indicator (won’t repeat for 100 years)
  – Sequential number (999,999/facility/year)
• Additional elements – NOT part of Donation Number
  – Flag characters
  – Manual entry check character (Eye readable only)
  – Data Identifier (Bar code only)

Donation Number – Flag Characters

• Flag characters are NOT part of the Donation Number
• Are used for process control
• Will NOT be the same on component label as on label applied at collection or what is printed on packing slips
• Are encoded in the bar code and printed on labels and reports
Keyboard Entry Check Character

- Keyboard entry into computer system should be strongly discouraged.
- When keyboard entry is necessary, computer software should be designed to recognize manual entry and require entry of Check Character for verification of data entered.
- Check character required for manual entry of long numbers (e.g., donation number and red cell antigen testing)
- Not in the bar code because it’s meant to check KEYBOARD entry

Manual Transcription - Donation Number

- A minimum of the 13 digit donation number is required for traceability of the component
  - Same 6 digit serial number may be used by all CBS blood collection sites in same year.
  - Must have 5 digit facility identifier and 2 digit year to make donation number unique and traceable back to the donor.
  - Recording of flag characters and manual check character is optional.
Blood Groups

ISBT 128 Data Structure 002

**Blood Groups Data Structure 002**

```
=%ggre
```

- **%**: Data identifier
- **gg**: ABO & Rh blood group and type of donation or collection information
- **r**: Optional. If used provides Rh, Kell phenotype as part of blood group structure
- **e**: Reserved for future use. Value always set to 0 (zero)
Blood Groups – Data Structure 002

• Coding for ABO, Rh & Type of Donation
  – ISBT 128 Technical Specification, Table 5
  – Donation Types used by Canadian Blood Services
    • Default/Not Specified (Volunteer Homologous Donations)
    • Directed (Dedicated/Designated) Collection Use Only
    • For Autologous Use Only
    • For Autologous Use Only/Biohazard

• Data Structure 002 Tables NOT used by Canadian Blood Services
  – Special Messages (Table 6)
  – Coding and Interpretation for Rh, Kell, Mi\textsuperscript{a}/Mur Phenotypes (Table 7)

  Note: Table 7 is used by Héma-Québec

Blood Groups

• Barcode indicates donation type (e.g. Autologous, Directed) as well as ABO/Rh, e.g.
  – O Positive, Use not specified – 5100
  – O Positive, Autologous Use Only – 5300
  – O Positive, Directed Use Only – 4900

• Rh not required for plasma components
  – ABO Group only will be encoded in barcode and printed on labels, e.g.
    • O, Use not specified – 5500
    • A, Use not specified - 6600

• Rh of Pooled Platelets
  – Will be labelled as Rh positive if "mixed" Rh in pool
Product Code

ISBT 128 Data Structure 003

ISBT 128 Product Codes & Definitions

• Product Code Database maintained by ICCBBA. All products distributed nationally/internationally must have a standard ISBT 128 product code.
Product Code Data Structure 003

\[ \text{=<aoooootds} \]

- Data identifier
- Product code
- Donation type (e.g. Volunteer, Directed)
- Divisions A0, B0,
- Second level divisions Ba, Bb, Bc

ISBT 128 Product Codes & Definitions

- 8 digit product code data structure includes donation type and allows for definition of additional information
- 5 digit ‘core’ product code which defines
  - Core conditions – e.g. anticoagulant, volume, storage conditions
  - Component Class - e.g. Red Blood Cells, Platelets
  - Modifiers – e.g. washed, thawed
  - Attributes – e.g. irradiated, residual white count, low platelet count
- 3 digits define donation type and divisions/splits
Example of ISBT 128 Product Code

- Component Class: Red Blood Cells
- Modifier: None
- Core Conditions
  - Anticoagulant: CPD, SAGM Added
  - original volume: 500 ml
  - storage conditions: refrigerated
- Attributes: Irradiated, Leukoreduced

ISBT PRODUCT CODE = E6051

Type of Donation

6th Character

- Sixth character identifies donation type
  - E6051V00
  - V = Volunteer Donor*
  - 1 = Autologous Use Only
  - 2 = Directed Use Only
  - X = Autologous Biohazard

* Volunteer homologous (allogeneic) donation (default)
Divisions/Splits

E6051V00 (Original product)
RED BLOOD CELLS/CPD>SAGM/from 500 mL whole blood/refrig

E6051VA0 (Divided from original – e.g. pediatric)
RED BLOOD CELLS/CPD>SAGM/from 500 mL whole blood/refrig/Divided

E6051VAA (Divided from first level division (e.g. syringe))
RED BLOOD CELLS/CPD>SAGM/from 500 mL whole blood/refrig/Divided

Product Codes – Codabar vs ISBT 128

No one to one relationship between Codabar & ISBT 128.

Codabar ‘Core” Product Code E6051

ISBT 128 Product Codes include:
Volunteer Donor E6051V00
Autologous E6051100
Directed E6051200
Volunteer Donor, Divided Part 1 E60511A0
Etc……
Expiration Date and Time

ISBT 128 Data Structure 005

Expiration Date & Time

Data Structure 005

>&cyyjjjhhmm

>& Data identifier
c Century in which product expires
yy Year within the century in which product expires
jjj Julian day of the year on which product expires
hh Hour at which product expires (00 to 23)
mm Minute at which product expires (00 to 59)
Collection Date and Time

ISBT 128 Data Structure 007

Collection Date & Time
Data Structure 007

&*cyyjjjhhmm

&* Data identifier
c Century in which product was collected
yy Year within the century in which product collected
jjj Julian day of the year on which product collected
hh Hour at which product collected (00 to 23)
mm Minute at which product collected (00 to 59)

Note: Used for all components except Pooled Platelets.
Production Date and Time

ISBT 128 Data Structure 009

\[ &\}cyyjjjhhmm \]

\&} Data identifier

c Century in which product was produced

yy Year within the century in which product produced

jjj Julian day of the year on which product produced

hh Hour at which product produced (00 to 23)

mm Minute at which product produced (00 to 59)

**Note:** Used only for Pooled Platelets
Special Testing: General

ISBT 128 Data Structure 010

&{(zzzzz

Data identifier

zzzzz 5 digit alphanumeric data content string (A-Z;0-9)

• Data content string encoded and interpreted with reference to Special Testing database table, published and maintained by ICCBBA.
Special Testing: General
Data Structure 010

Purpose:
• Indicates special characteristics of a product, e.g. CMV antibody status, IgA deficiency
• Will be found on labels of platelet and plasma products produced by Canadian Blood Services

Special Testing: Red Blood Cell Antigens - General
ISBT 128 Data Structure 012
Special Testing: Red Blood Cell Antigens
- General    Data Structure 012

\`\`\`\`\`\`\`
Data identifier
\`\`\`\`\`\`\`
aaaaaaaaaaaaaaaaaii 18 character data content string (0-9)

- Data content string encoded and interpreted using Table 10 in ISBT 128 Standard Technical Specification (ICCBBA)

Special Testing: Red Blood Cell Antigens
Data Structure 012

- Will be on labels of whole blood and red blood cell components produced by Canadian Blood Services
- Canadian Blood Services will encode Rh antigens individually using positions 14, 15 and/or 16 and value of column 1 will be set to 9 (no information)
- If additional red cell antigen testing has been performed but cannot be encoded in the bar code structure, the information will appear on the label in eye readable form
- Rules for printing of eye readable red cell phenotype (e.g bold, underline) will not change with ISBT 128 implementation.
For more information on ISBT 128 implementation at Canadian Blood Services:
www.transfusionmedicine.ca