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
Information Hierarchy

- Definitions
- Reference Tables
- Data Structures
- Delivery Mechanisms
- Labeling
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

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

<table>
<thead>
<tr>
<th>CODE</th>
<th>NAM CODE</th>
<th>RFORM</th>
<th>PRODD ESCRIP CODE</th>
<th>PRODDESCRIP0</th>
<th>CODEDATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1122</td>
<td>002</td>
<td>@29G3</td>
<td></td>
<td>Cryopreserved HPC, MARROW</td>
<td>NS/XX/&lt;=-150C</td>
</tr>
<tr>
<td>S1123</td>
<td>006</td>
<td>@29G3</td>
<td></td>
<td>Cryopreserved HPC, APHERESIS</td>
<td>NS/XX/&lt;=-150C</td>
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<tr>
<td>S1124</td>
<td>010</td>
<td>@29G3</td>
<td></td>
<td>Cryopreserved HPC, CORD BLOOD</td>
<td>NS/XX/&lt;=-150C</td>
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<td>S1125</td>
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<td>@28H3</td>
<td></td>
<td>HPC, MARROW</td>
<td>Heparin/XX/refg</td>
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<tr>
<td>S1130</td>
<td>009</td>
<td>@34</td>
<td></td>
<td>HPC, CORD BLOOD</td>
<td>Citrate/XX/refg</td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Element</th>
<th>Length</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>=</td>
<td>1</td>
<td>data identifier, first character</td>
</tr>
<tr>
<td>%</td>
<td>1</td>
<td>data identifier, second character</td>
</tr>
<tr>
<td>gg</td>
<td>2</td>
<td>alphanumeric {A–Z; 0–9}</td>
</tr>
<tr>
<td>r</td>
<td>1</td>
<td>alphanumeric {A–Z; 0–9}</td>
</tr>
<tr>
<td>e</td>
<td>1</td>
<td>alphanumeric {A–Z; 0–9}</td>
</tr>
</tbody>
</table>
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”)

Copyright ICCBBA, Inc
Location of bar codes on 100 mm x 100 mm Label

- Donation Identification Number
- Collection Date
- Product Code

- ABO/Rh
- Expiration Date
- Special Testing
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