ISBT 128

International Coding System for Blood, Tissues and Cells

Paul Ashford

History

- Blood transfusion was one of the earliest applications in healthcare to use bar coding
- CCBBA formed in 1974 to address errors in transfusion events
- ABC Codabar Standard developed in early 80's
- 1985 - FDA published "Guideline for the Uniform Labeling of Blood and Blood Components"

History

"This [1985] guideline had the stated objective of reducing the dangers of transfusion caused through human errors by presenting important information on the label in a clear and logical format; it proscribed exactly where to place the eye-readable and bar code scanner–readable label information about the collecting center, blood type, component type, collection and expiration dates, and bag manufacturer information."

Wallas C. Transfusion 2005

History

- Bar coding was essential to ensure correct association between samples, donations and documentation
- Primarily used at Blood Centres
- Hospital blood banks typically only received blood from a single Blood Centre

Problems with Codabar

- Misreads
- Seven digit identifier – not unique between organisations
- Re-cycling of numbers
- Product code capacity inadequate
- No management system
- Breakdown in product code assignment

First Gulf War

- Blood sourced from many countries and blood centres
- Duplicate numbers
- Product code mismatches – exacerbated by multiple language
- Traceability difficulties

WPADP

- International Society of Blood Transfusion
- Working Party on Automation and Data Processing – sponsored to develop a new standard
- 1994 – published a new standard based on Code 128 barcodes - *ISBT 128*
- Established ICCBBA as not for profit body to manage the new standard

ISBT 128
More than Identification

What is *ISBT 128*?

- *ISBT 128* is an international standard for the coding and labeling of blood components, cellular therapy products, tissue and organ transplant products.
- Provides a standard coding system that:
  - supports the open movement of blood, tissues and cellular therapy products around the world in such a way that critical information is rapidly, accurately and unambiguously communicated;
  - satisfies regulatory requirements;
  - support traceability and retention of information.

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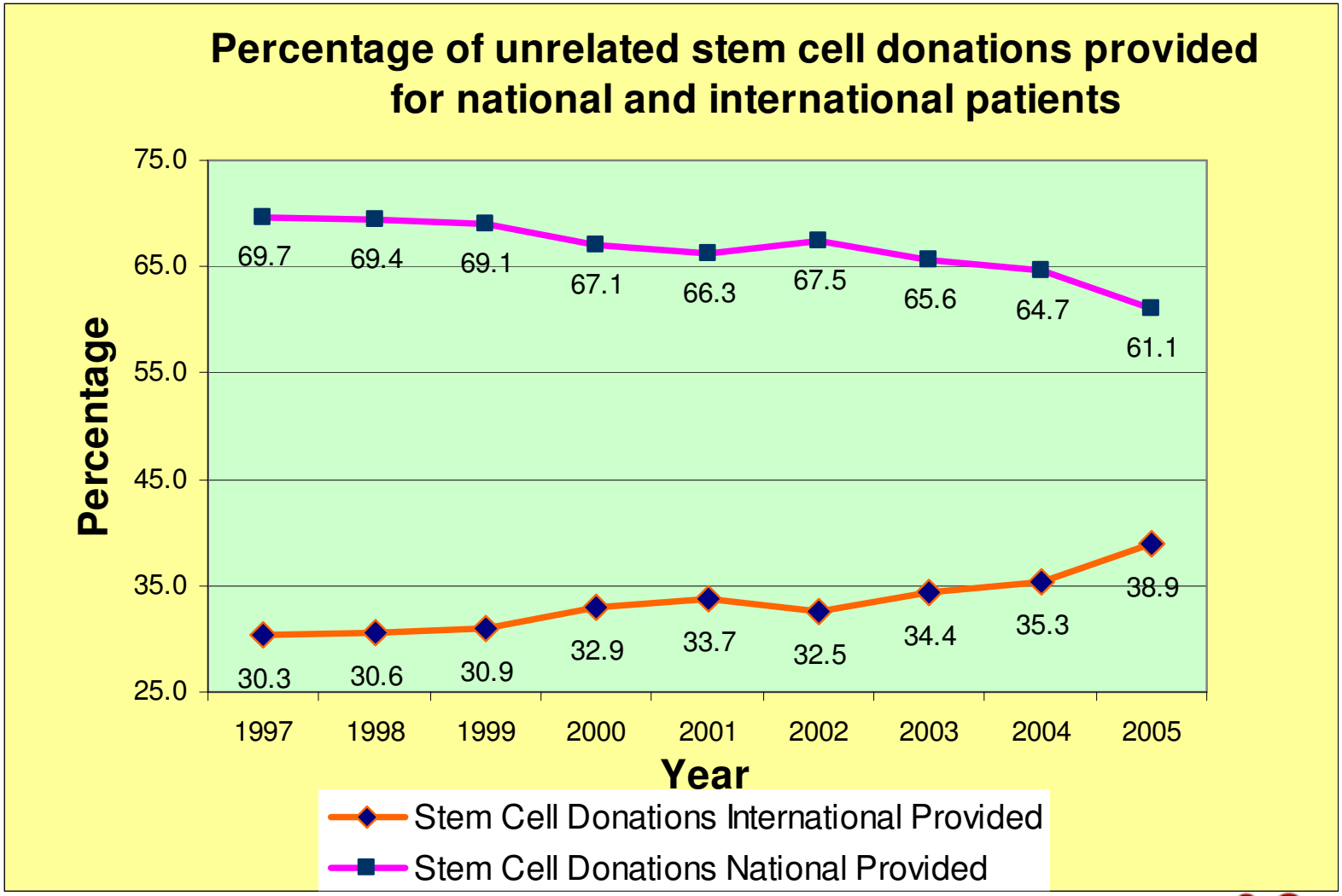
International Movement



Regulatory Requirements

- European Directive 2002/98/EC – setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
  - Article 14 Traceability
  - Article 15 Notification of Serious Adverse Events and Reactions

Art. 14 - Traceability

- Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.
- To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component.

Art. 14 - Traceability

- Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.
- *(30 years from time of use, some products may be stored in liquid nitrogen for 10 years or more before use)*

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Art. 15 - Serious Adverse Events

- Member States shall ensure that:
  - *(serious adverse events are notified)*
  - blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

Key Elements of *ISBT 128*

- Unique donation numbering system (global)
  - G151707123456
- International product list, definitions and codes
  - E3214 - Apheresis PLATELETS|ACD-B/XX/20-24C|Irradiated|ResLeu:<5log6
- Standard structures and formats for a wide range of information – allows interoperability
- Mechanism and organisation for development and maintenance of the standard

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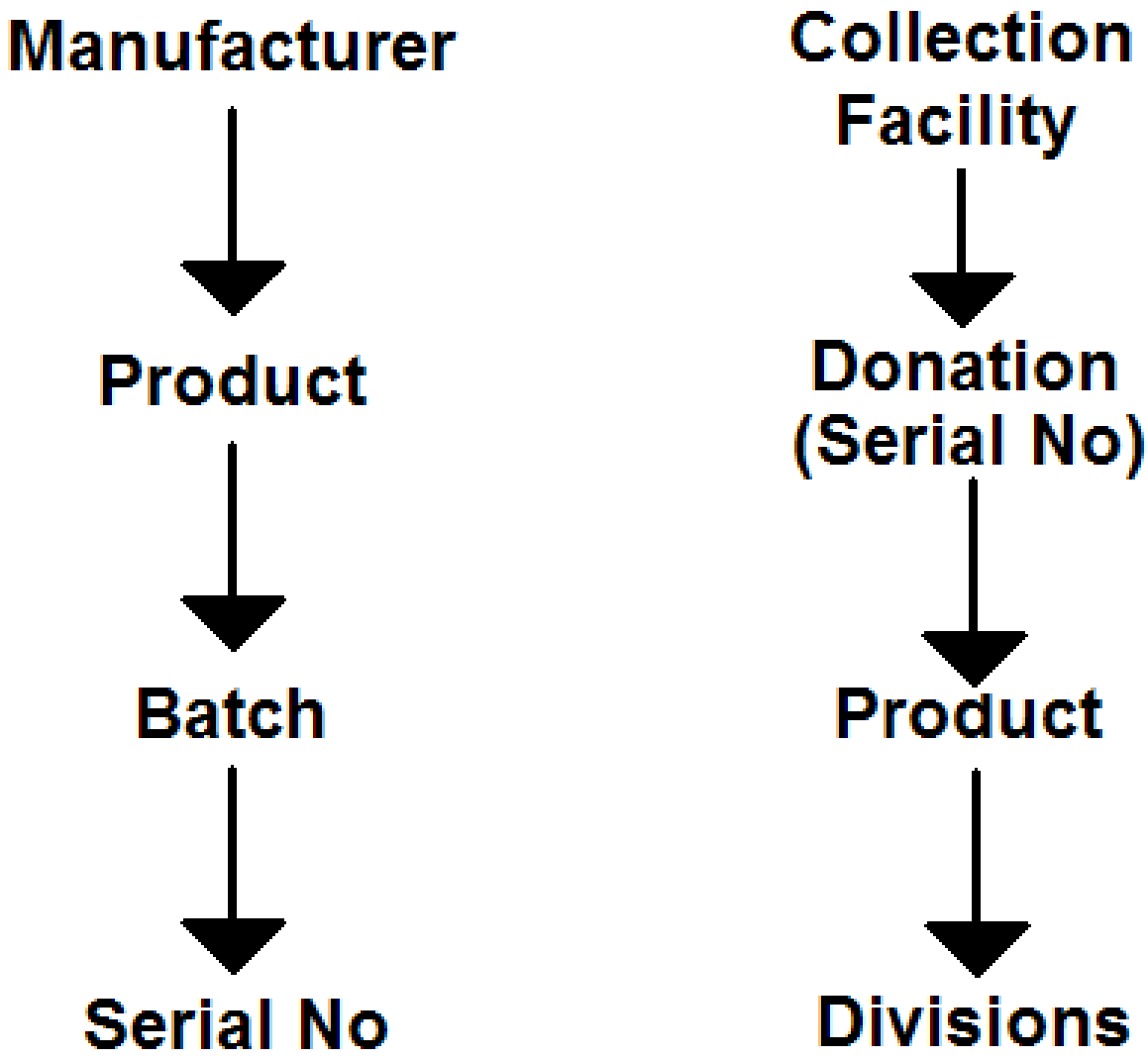

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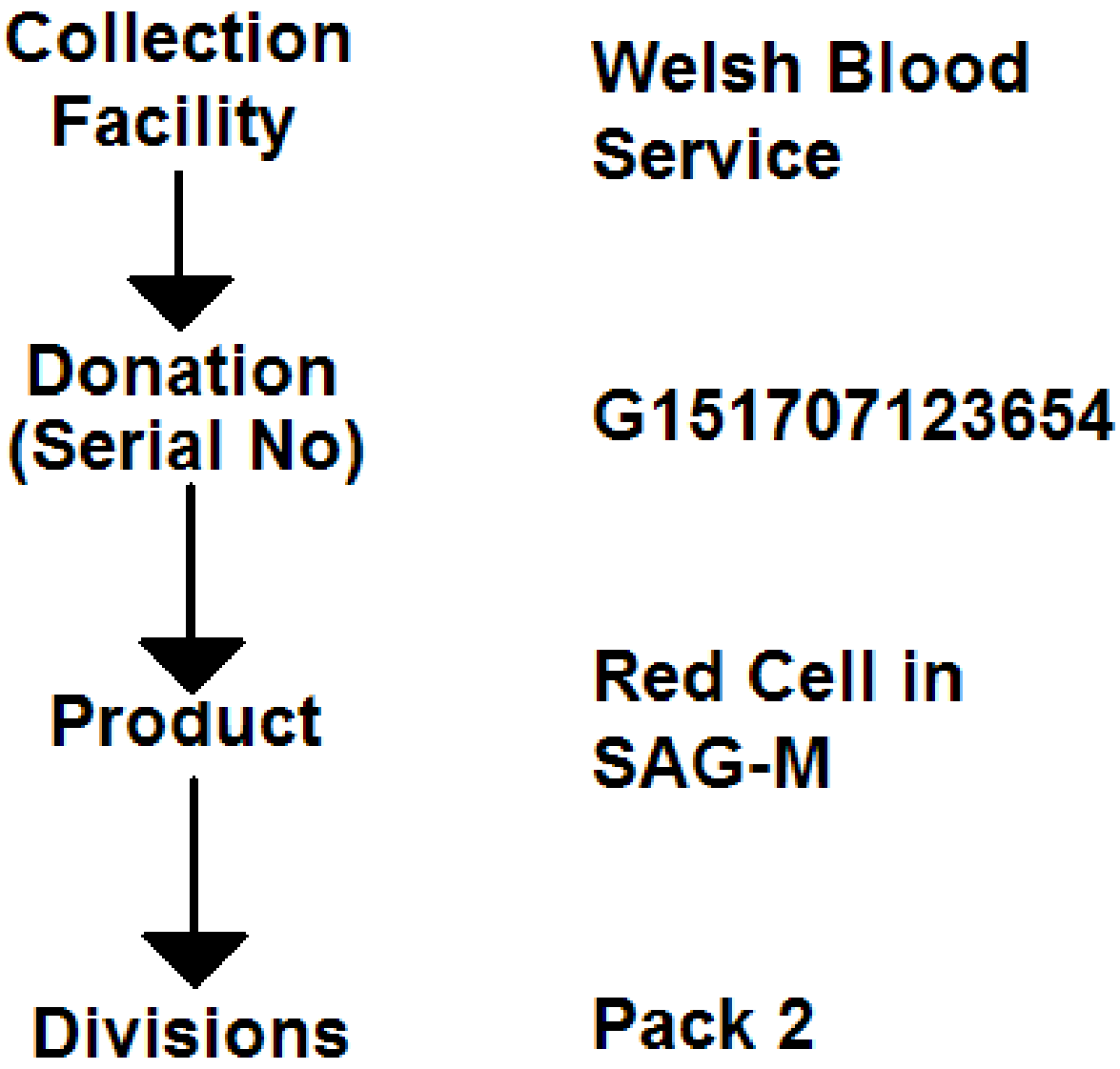

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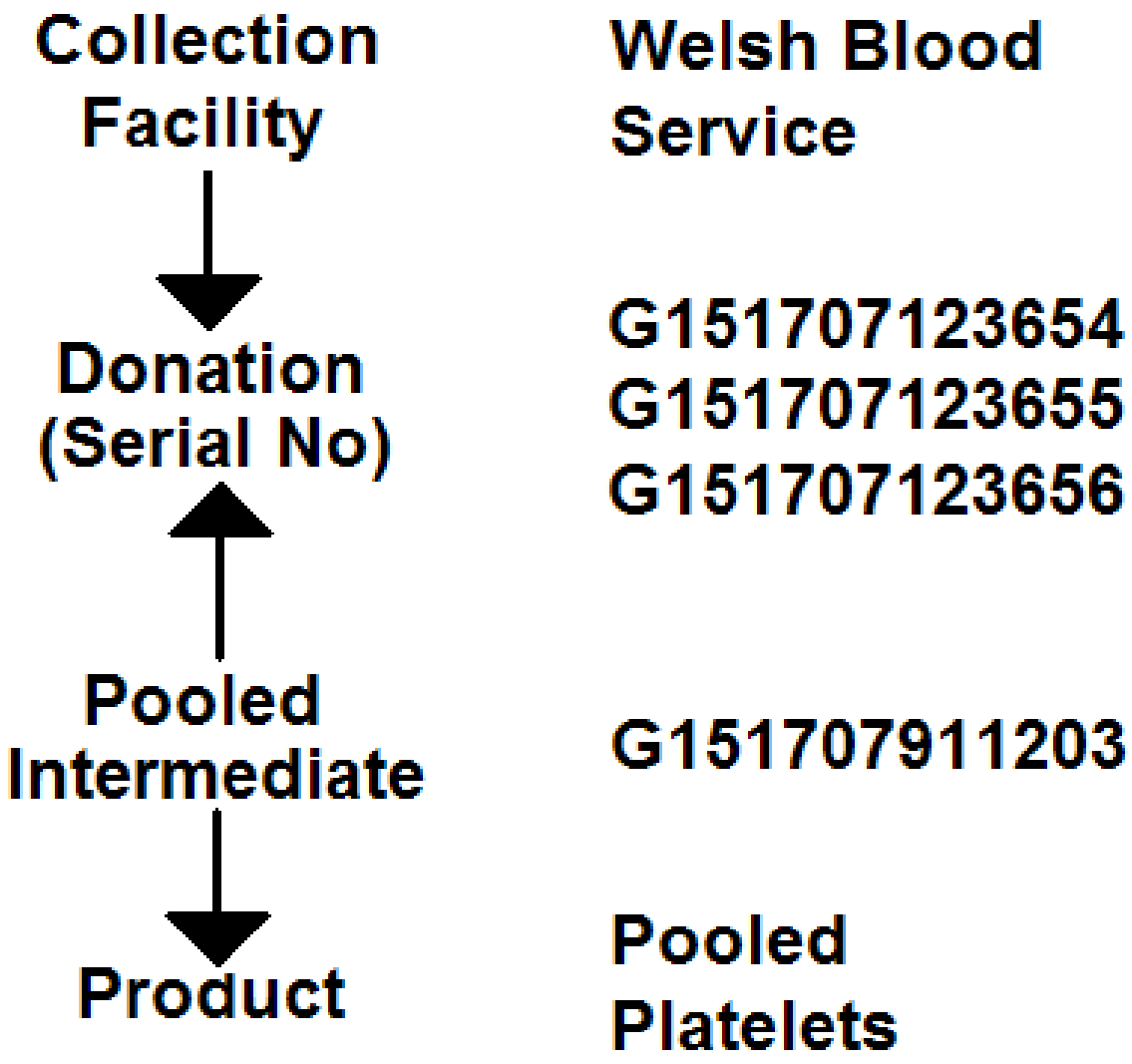

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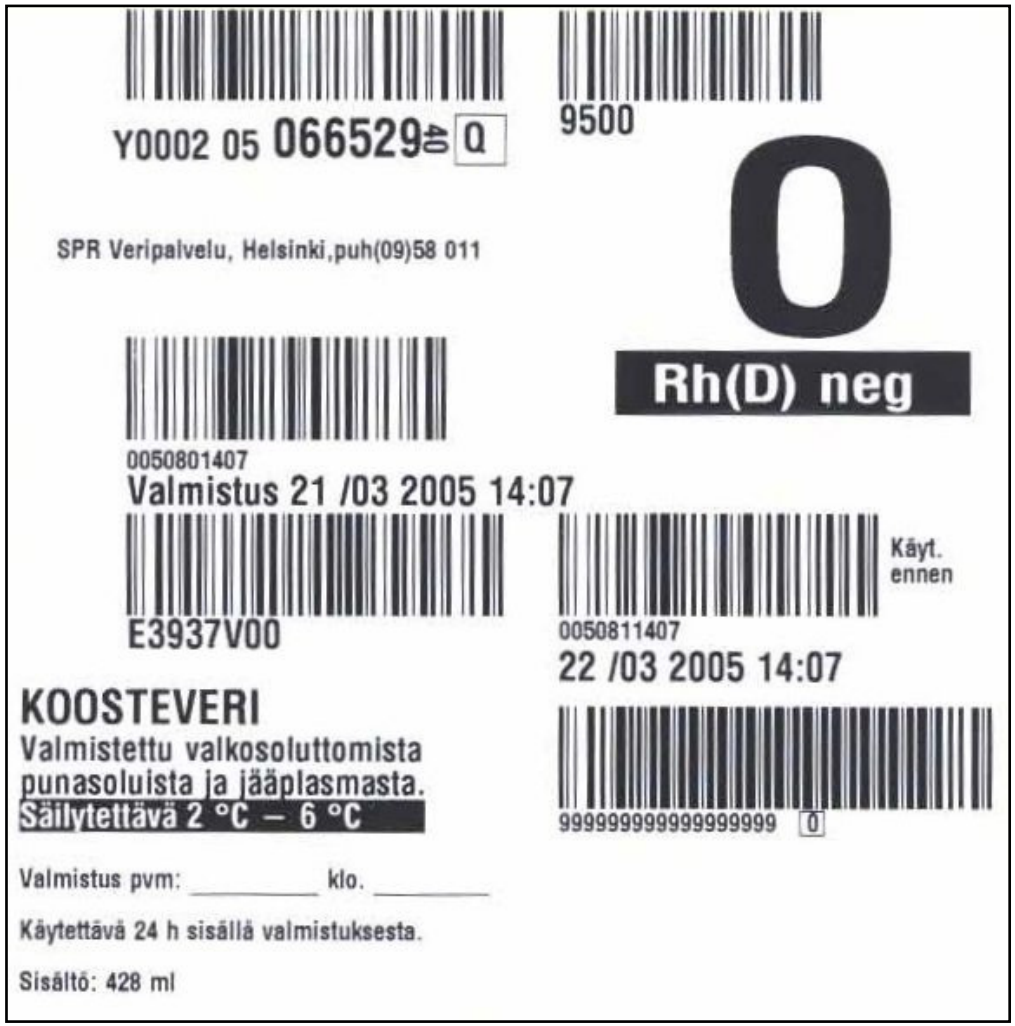
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9500
SPR Veripalvelu, Helsinki,puh(09)58 011
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Rh(D) neg
0050801407
Valmistus 21 /03 2005 14:07
E3937V00
0050811407
Käyt. ennen
22 /03 2005 14:07
KOOSTEVERI
Valmistettu valkosoluttomista punasoluista ja jääplasmasta.
Säilytettävä 2 °C – 6 °C
99999999999999999 0
Valmistus pvm: _____ klo. _____
Käytettävä 24 h sisällä valmistuksesta.
Sisältö: 428 ml


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Rh(D) neg
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Valmistus 21 /03 2005 14:07
E3937V00
Käyt. ennen
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22 /03 2005 14:07
KOOSTEVERI
Valmistettu valkosoluttomista punasoluista ja jääplasmasta.
Säilytettävä 2 °C – 6 °C
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Valmistus pvm: _____ klo. _____
Käytettävä 24 h sisällä valmistuksesta.
Sisältö: 420 ml


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Valmistus 21 /03 2005 14:07
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Käyt. ennen
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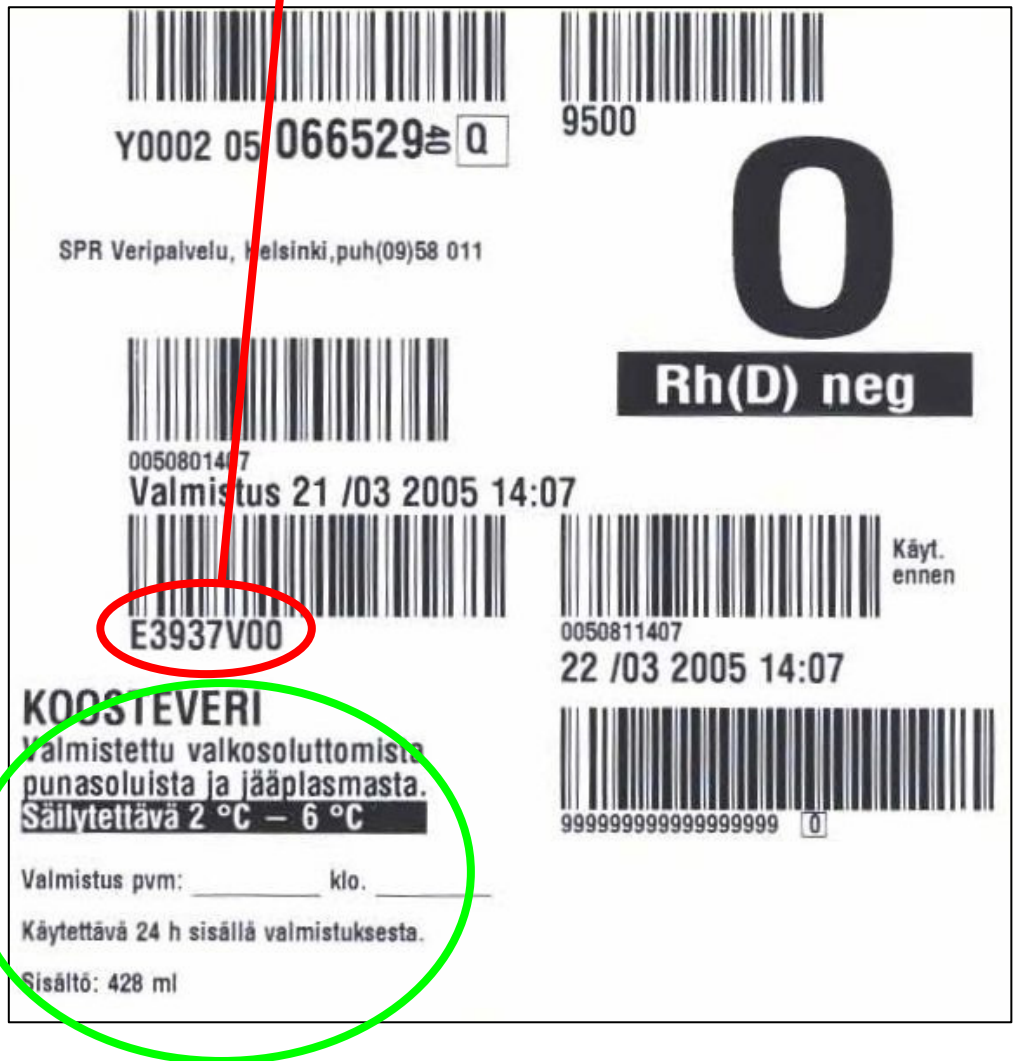
22 /03 2005 14:07
KOOSTEVERI
Valmistettu valkosoluttomista punasoluista ja jääplasmasta.
Säilytettävä 2 °C – 6 °C
99999999999999999 0
Valmistus pvm: _____ klo. _____
Käytettävä 24 h sisällä valmistuksesta.
Sisältö: 428 ml

PRODD	PRODDESCRIPCODEFORM	PRODDESCRIP0
E3934	E012E@AJEA2EG7	Apheresis FRESH FROZEN PLASMA|ACD-A/XX/<-30C|For mnf:injectable|Frozen <=24h
E3935	E042E@64EA2	PLATELET RICH BUFFY COAT|CPD/450mL/20-24C|For mnf:injectable
E3936	E002E@03EC2ED5EE5	RED BLOOD CELLS|CPD/450mL/refg|Irradiated|ResLeu:<1log6|Plasma reduced
E3937	E002E@03ED5EE9	RED BLOOD CELLS|CPD/450mL/refg|ResLeu:<1log6|Plts/Cryo reduced
E3938	E002E@03EC2ED5EE9	RED BLOOD CELLS|CPD/450mL/refg|Irradiated|ResLeu:<1log6|Plts/Cryo reduced
E3939	E003E@24ED5	Washed RED BLOOD CELLS|SAGM/450mL/refg|ResLeu:<1log6
E3940	E003E@24EC2ED5	Washed RED BLOOD CELLS|SAGM/450mL/refg|Irradiated|ResLeu:<1log6



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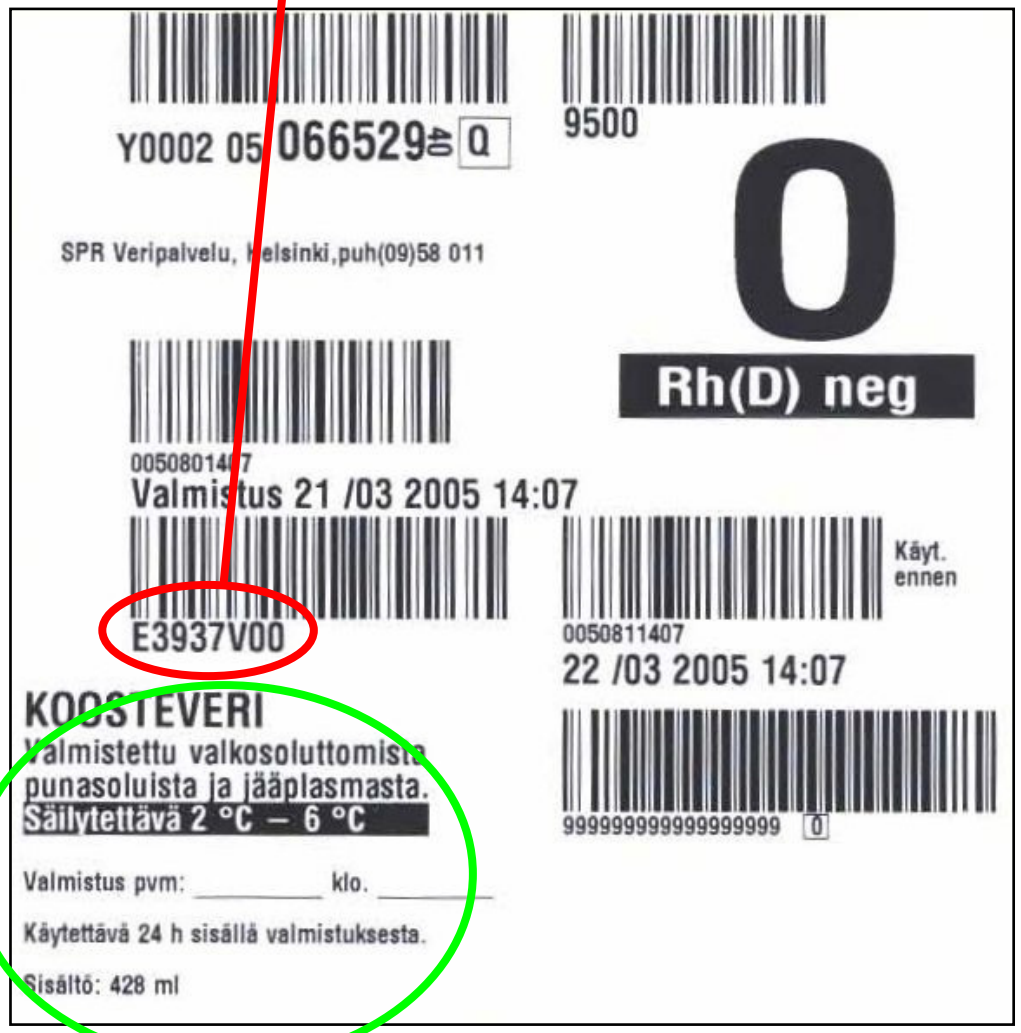
E3937	E002E@03ED5EE9	RED BLOOD CELLS|CPD/450mL/refg|ResLeu:<1log6|Plts/Cryo reduced
E3938	E002E@03EC2ED5EE9	RED BLOOD CELLS|CPD/450mL/refg|Irradiated|ResLeu:<1log6|Plts/Cryo reduced
E3939	E003E@24ED5	Washed RED BLOOD CELLS|SAGM/450mL/refg|ResLeu:<1log6
E3940	E003E@24EC2ED5	Washed RED BLOOD CELLS|SAGM/450mL/refg|Irradiated|ResLeu:<1log6



RED BLOOD CELLS

CPD, 450ml, refg

Res Leucocytes < 1 x 10^6

Plts & Cryo reduced

Labeling

- Based on principles of good labeling
- Based on established *ISBT 128* label design
- Adapted for different container sizes
- Consistent across different languages
- Balance of human and machine readable information

ISBT 128
More than Identification

Principles of Good Labeling

- Clear
- Carry sufficient information
- Critical information emphasised
- Capable of being read by machines and humans
- Consistent
- Compatible with printing and reading technologies
- Compliant with regulatory requirements

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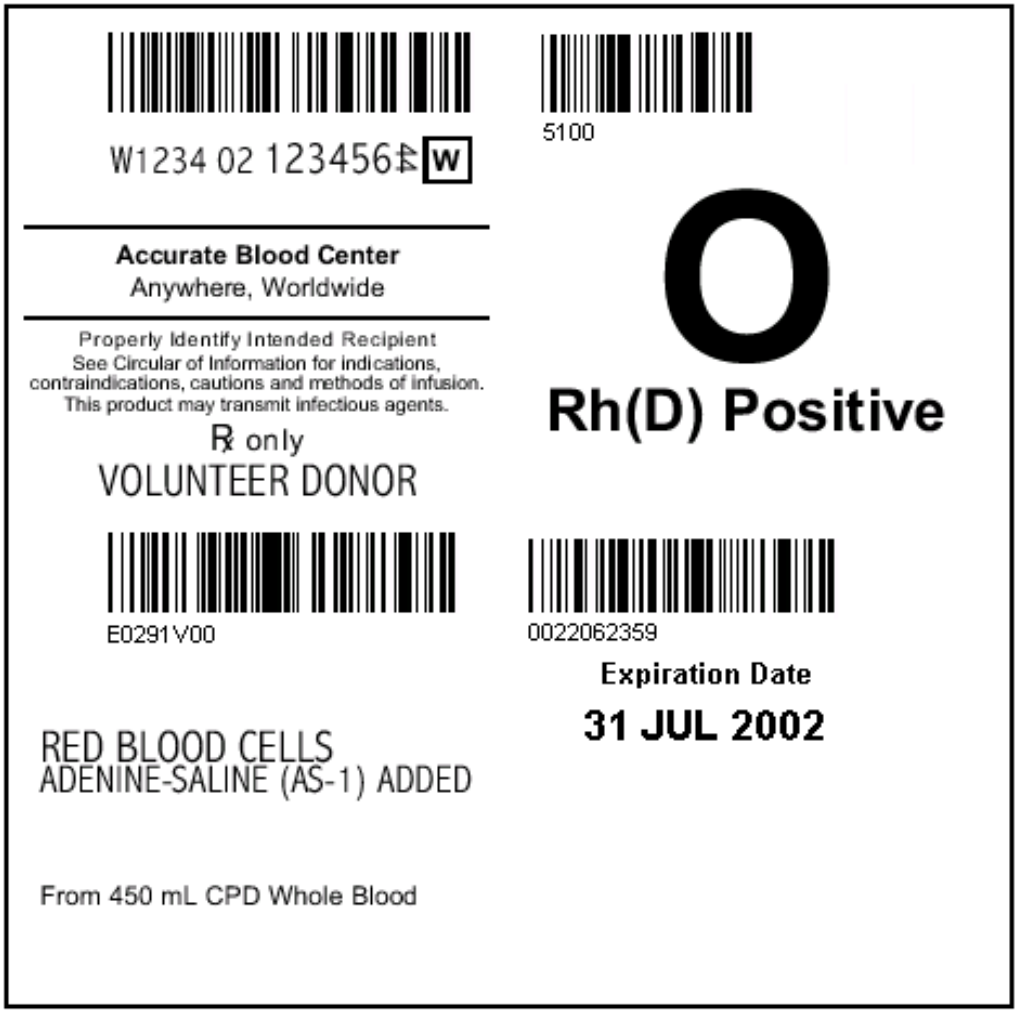
ISBT 128 Labelling



Donation Identification Number

Blood Group

Product Code

Expiration Date

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Use of *ISBT 128*

- Over 3,300 Licensed Facilities worldwide
- Rapid growth: over 2,000 Licensed Facilities added this year to date
- 30 million units of blood *ISBT 128* labeled each year
- 73 Licensed Vendors including bag manufacturers, software developers, lab equipment manufacturers
- *ISBT 128* compliant products

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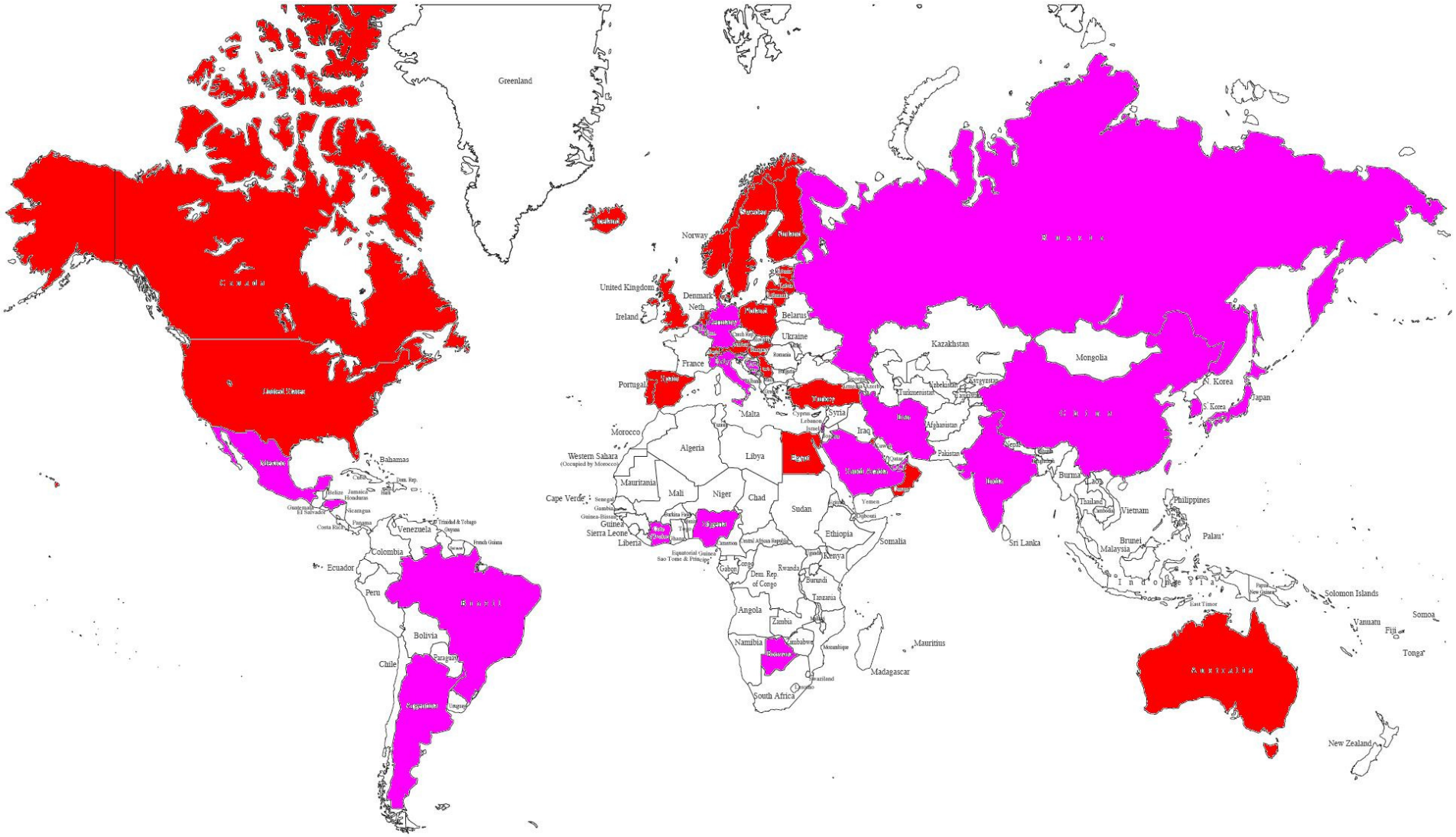
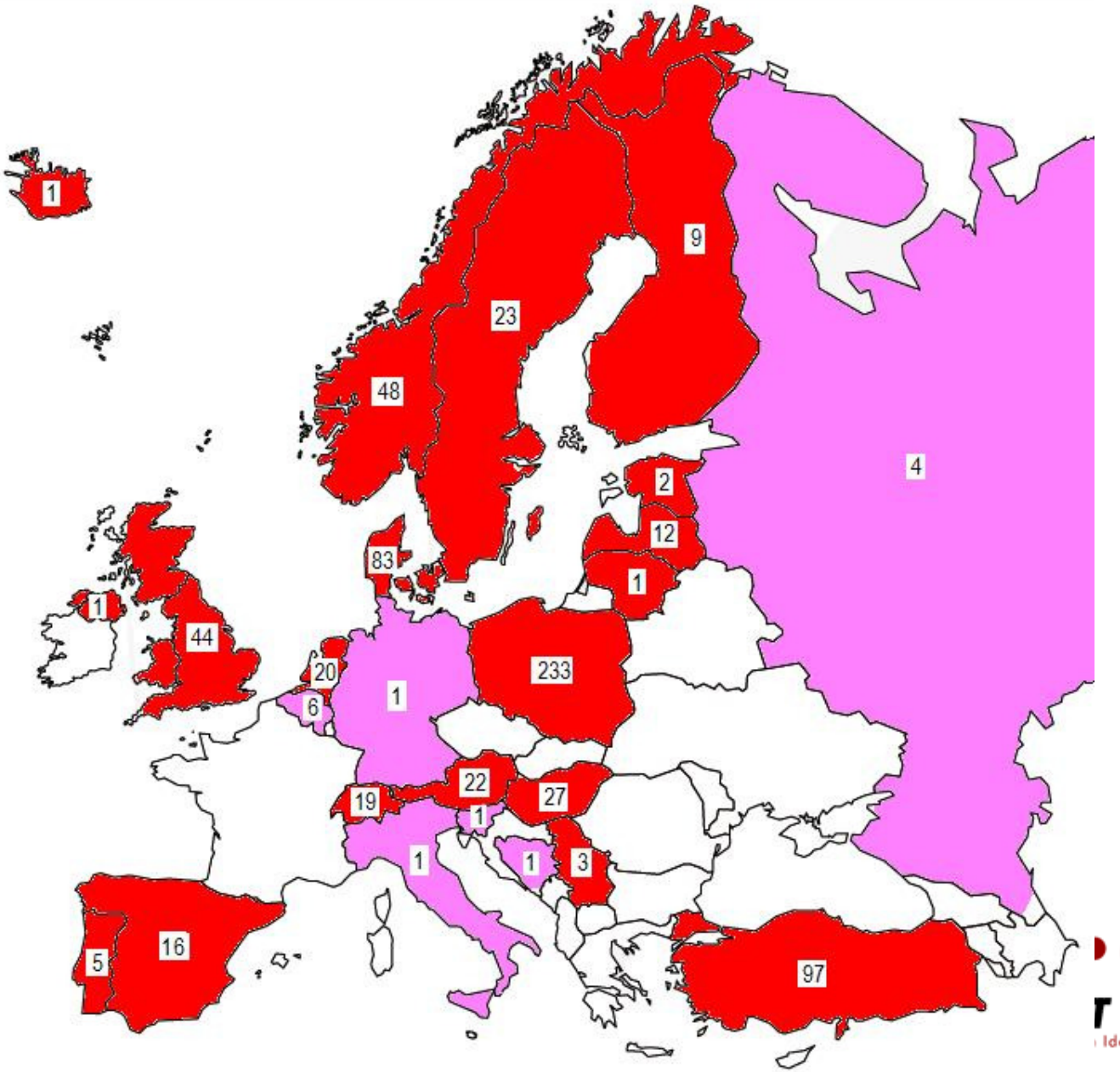
Countries with ISBT *128* Licensed Facilities



Licensed Facilities in Europe



ICCBBA

- Established in 1995 by AABB, ARC and ISBT
- Not-for-profit organization
- Head office in CA, USA
- Mission Statement:
  - ICCBBA enhances safety for patients by managing the ISBT 128 international information standard for use in transfusion and transplantation

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Management

- Management by ICCBBA delivered through a small staff.
- Administrative team deals with allocation of codes and user liaison
- Technical team supports standard documentation and development, technical liaison and education.
- Wide involvement of the user community through Technical Advisory Groups (TAGs) to ensure *ISBT 128* meets user needs
- Liaison with relevant Standards Bodies, Regulators and Professional Organisations

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Activities

- Assign and control key identifiers, databases and reference tables
- Manage product database
  - Assign new codes
  - Develop to support new procedures
- Manage and update standard documentation
- Liaise with user and vendor communities
- Future development process
- Education

Working with GS1

- Manufacturer information for blood bags – carton vs individual unit
- Plasma derivative coding (albumin solutions, immunoglobulins)