



ISBT 128 Bar Code Labeling: Impact on Hospitals

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BioArch Program

[Purpose

To understand the issues facing hospitals as they prepare for the conversion to ISBT 128-labeled blood products

[Outline

- Why change to ISBT 128?
- Highlights of ISBT 128 changes
- More detail about the changes
- Other changes taking place
- Assess organizational impact
- How should hospitals plan for conversion?
- Additional references

[Why change to ISBT 128?

- AABB requirement by May 2008
- All major blood centers will convert

Why change to ISBT 128?

■ Limitations of Codabar

- Codabar is susceptible to substitution errors and misscans
- Product code structure not updated to reflect proliferation of new blood products
- No provision to maintain the system

Highlights of ISBT 128 Changes

- Appearance of the label
 - Layout will be different than current label
 - Globally consistent appearance
- Different bar code technology
 - From ABC Codabar to ISBT 128 symbology
 - Globally consistent bar code symbology
- Structure of donation identification number (DIN)
 - Formerly WBN
 - 13 digits instead of 8
 - Globally unique number

Highlights of ISBT 128 Changes

- Product code
 - From 4 digits to 8 digits
 - From 100 product codes to 1400
 - Globally consistent product codes
- Expiration date
 - May show the time of expiration
 - Globally consistent expiration dating

More Detail About the Changes

- Bar code technology
 - ABC Codabar
 - Used for several decades
 - Code 128
 - Stores more data in this bar code
 - ISBT 128
 - Code 128 made specific for blood

More Detail About the Changes

Donation Identification Number

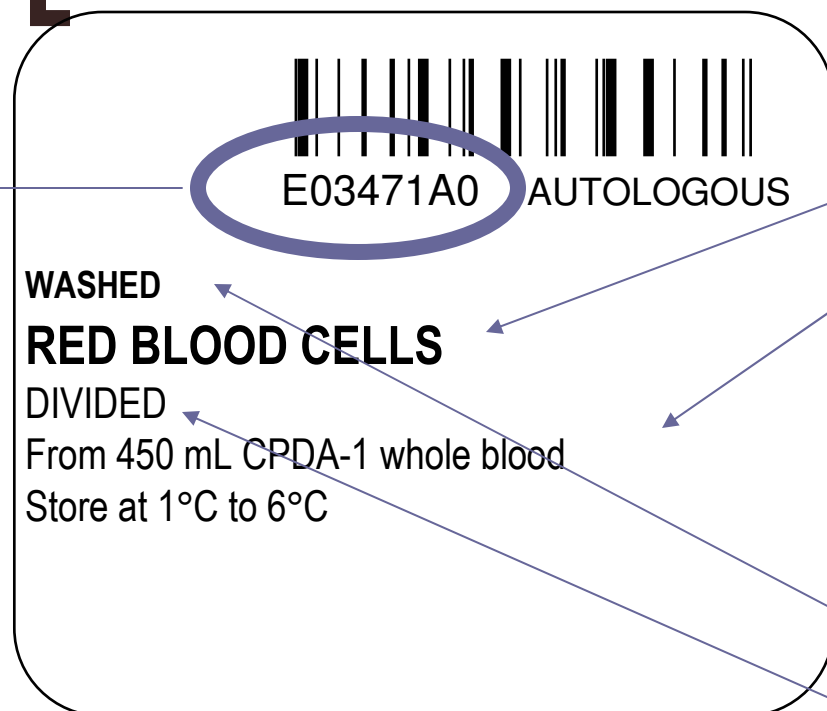


W	Position 1	Country identifier W has been assigned for the US
2000	Positions 2 to 5	A four-digit facility identification number for the American Red Cross 2009 identifies Midwest Region
YY	Positions 6 and 7	A two-digit year of collection (eg, 2005 would be represented as "05")
NNNNNN	Positions 8 to 13	A sequential six-digit number assigned to each blood collection
8	Positions 14 and 15	Flag characters for process control
K	Letter in a box is checksum character	Used only when the number is manually entered into the system as a check against errors

More Detail About the Changes

- Product codes
 - Globally recognized
 - 2600 ISBT 128 product codes
 - American Red Cross will use approximately 1400
 - 8-digit product code represents
 - Product class (RBC, plasma)
 - Modifiers (washed, frozen)
 - Attributes (irradiated, for research)
 - Donation type (autologous, allogeneic, directed)
 - Divided unit status (first division, second division)

More Detail About the Changes



Component
Class=red blood cells

Core conditions
Anticoagulant=CPDA-1
Vol of collection=450 mL
Storage temp=1°C to 6°C

Modifier=washed
Attribute=divided

E0347=product code
1=donation type autologous
A0=divided 1st portion

More Detail About the Changes

Comparison of Codabar to ISBT 128 Product Codes

Codabar Product Code	Codabar Product Name	ISBT Product Bar Code	ISBT Divided Code	ISBT Product Name	US Product Name
04710	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED	E0301	00	RED BLOOD CELLS CPD>AS1/450mL/refg Open ResLeu:<5log6	RED BLOOD CELLS CPD>AS1/450mL/refg Open ResLeu:<5log6
04710	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED	E0311	00	RED BLOOD CELLS CPD>AS1/450mL/refg ResLeu:<5log6	RED BLOOD CELLS CPD>AS1/450mL/refg ResLeu:<5log6
04710	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED	E0326	00	RED BLOOD CELLS CPD>AS1/500mL/refg Open ResLeu:<5log6	RED BLOOD CELLS CPD>AS1/500mL/refg Open ResLeu:<5log6
04710	AS-1 RED BLOOD CELLS LEUKOCYTES REDUCED	E0336	00	RED BLOOD CELLS CPD>AS1/500mL/refg ResLeu:<5log6	RED BLOOD CELLS CPD>AS1/500mL/refg ResLeu:<5log6

More Detail About the Changes

Expiration Labels

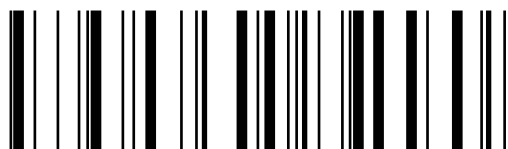


0022942359

Expiration
Date/Time

27 NOV 2002

When time default of 2359 is used, it is not necessary to show time in eye-readable text; midnight expiration is assumed.



0022941645

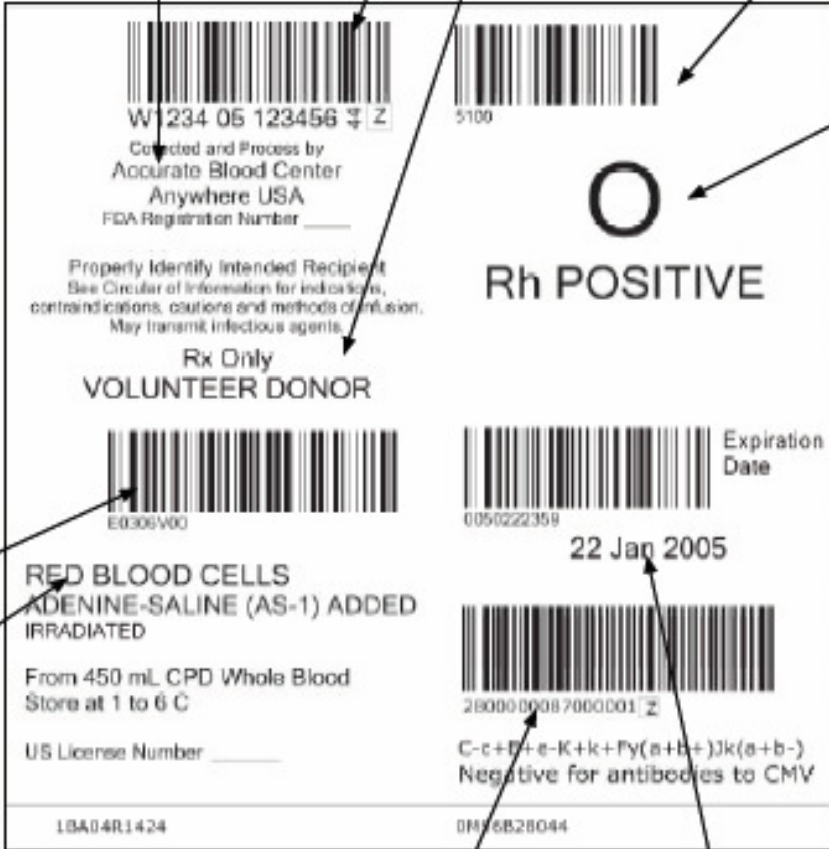
Expiration
Date/Time

27 NOV 2002 16:45

For time sensitive products

More Detail About the Changes

Full Face Label



DONOR IDENTIFICATION

BLOOD CENTER

DONOR STATEMENT

ABO/RH BAR

ABO/RH TEXT

PRODUCT CODE

PRODUCT INFORMATION

SPECIAL TEST

EXPIRATION DATE

W 1234 05 123456 Z

Collected and Processed by
Accurate Blood Center
Anywhere USA
FDA Registration Number _____

Properly Identify Intended Recipient
See Circular of Information for indications,
contraindications, cautions and methods of infusion.
May transmit infectious agents.

Rx Only
VOLUNTEER DONOR

RED BLOOD CELLS
ADENINE-SALINE (AS-1) ADDED
IRRADIATED

From 450 mL CPD Whole Blood
Store at 1 to 6 °C

US License Number _____

18A04R1424

5100

0050222359

22 Jan 2005

2800000087000001 Z

C-c+D-e-K+k+Py(a+b+)Jk(a+b-)
Negative for antibodies to CMV

DMY6B28044

Other Changes Taking Place

- FDA requirement that all blood products have machine readable as well as eye-readable data
 - Includes aliquoting, pooling, or relabeling
 - Bar code required for facility ID number, DIN, ABO/Rh, product code
 - Does not include expiration dates
 - Does not differentiate between Codabar and ISBT 128

[Other Changes Taking Place

- AABB regulations
 - Have written plan for conversion by November 2006
 - Implement ISBT 128 by May 2008

Other Changes Taking Place

■ ICCBBA

○ Who are they?

- Formerly known as International Council on Commonality in Blood Banking Automation. Today, they are known by their acronym

○ What do they do?

- Responsible for worldwide administration
- Maintain databases of product codes, locations
- Assign site registration numbers
- Host technical advisory groups

Other Changes Taking Place

- ICCBBA requires some hospitals to register
 - This is not an American Red Cross requirement
 - American Red Cross is registered
- What hospitals should register
 - Required
 - Hospitals that collect units of blood
 - Hospitals that modify, pool, or relabel blood
 - Not required
 - Hospitals that do not modify blood components
 - Hospitals should contact ICCBBA with questions
 - <http://www.iccbba.com>

Assess Organizational Impact

- Software impact
 - Computer systems
 - Blood bank system, lab system, billing system
 - Ensure computer can read, translate, store, and process ISBT 128 data
 - 13 character DIN
 - 8 character product code
 - Expiration time and date
 - Computer must read both Codabar and ISBT 128

Assess Organizational Impact

- Software impact
 - Computer interfaces and interfaced systems
 - Ensure interfaces and interfaced systems can manage data
 - Billing systems
 - Lab equipment
 - Viral marker testing transfers
 - Reports (workload, operational, statistics)
- Even hospitals without computer systems will be impacted

[Assess Organizational Impact

- Procedure and forms impact
 - Review procedures
 - Will ISBT 128 changes require modifications?
 - Review forms
 - Accommodate 13 character DIN?
 - Accommodate 8 character product code?

Assess Organizational Impact

- Staff training impact
 - Blood bank staff
 - Transfusion staff
 - Floor staff
 - OR staff
 - Accounting/billing
 - Anyone who touches blood products
 - Anyone who scans blood product bar codes

Assess Organizational Impact

- Equipment impact
 - Ensure equipment can read ISBT 128 bar codes
 - Scanners
 - Printers
 - On-demand label printers
 - Lab equipment
 - Hematology, microbiology, chemistry
- Validation impact
 - Consider any changes to hardware, software, and equipment
 - Processes may need validation
 - Collections, aliquots, pools, modifications
 - SOPs

Assess Organizational Impact

- Financial impact
 - Software development cost
 - Upgrade/replace on-demand label printers
 - Upgrade/replace bar code scanners
- Product impact
 - Both Codabar and ISBT 128-labeled products will be shipped to hospitals
 - Codabar products with extended dates in inventory
 - Frozen products

How should hospitals plan for conversion?

- Establish a committee of stakeholders
- Determine anticipated conversion date
- Develop a plan
 - AABB members must have written plan by November 2006
 - AABB and ICCBBA have example plans
 - A web search will identify example plans

How should hospitals plan for conversion?

- Develop a budget
- Create a project management plan listing specific tasks, responsible people, and timeframes for completion
 - Work back from an anticipated conversion date

How should hospitals plan for conversion?

- Develop a communication plan
 - Notify management
 - Medical director/pathologist
 - Hospital administrator
 - IT manager
 - Notify other hospital departments
 - Impacted departments
 - Nursing, dialysis, anesthesiologists
 - Anyone who touches a blood bag
 - Impacted laboratories
 - Microbiology, chemistry, hematology
 - Anybody who scans an ISBT 128 bar code
- Consider other scheduled changes within the organization (change management)

Additional References

- AABB

- Sample ISBT-128 implementation plan

www.aabb.org/members_only/archives/other/isbt128plan.htm

- FDA

<http://www.fda.gov/cber/gdlns/ISBT128Nov99.pdf>

Additional References

- ICCBA, Inc.
 - ISBT 128 Standard: Technical Specification, Version 2.1.0, August 2004.
 - ISBT 128: Product Code Database (Blood Components)–Structure and Definitions, Version 1.3.0, June 2001.
 - ISBT 128 Standard: Product Coding: Bounded Lists and Definitions, Version 2.8, October 2005.
 - An Introduction to ISBT 128–A non-technical booklet useful for teaching.
 - An Introduction to Bar Coding–A non-technical booklet useful for teaching.
 - Technical Bulletin 1: Why Code 128? The Rationale Behind ISBT 128. March 1997.
 - Technical Bulletin 2: Secure On-Demand ISBT 128 Blood Container Label Printing. March 1997.
 - Technical Bulletin 3: On-Demand and Preprinted Labels: A Discussion and Bar Code Quality and Label Verification. April 1997.
 - Technical Bulletin 4: ISBT 128 Blood Product Coding, May 2004.
 - Technical Bulletin 5: Bar Code Scanner Implementation of ISBT 128 Concatenation, May 2001.
 - Technical Bulletin 6: EDI: Electronic Data Interchange, May 2001.
 - Technical Bulletin 7: Use of Flags in the Donation Identification Number for Process Control of Critical Points during Processing and Distribution, March 2005.
 - Technical Note 1: Case Conversion, May 2001.
 - Technical Note 2: Length of the Product Code Bar Code and Concatenation, June 2001.
 - Technical Note 3: ISBT 128 and Compound Message, May 2005.
 - Technical Note 4: Manufacturer's Catalog Number and Lot Number (NOT Containers).

Note: All ICCBBA, Inc., publications are available upon publication to registered and licensed facilities, software developers, and manufacturers through the ICCBBA, Inc.

Additional References

■ Others

- American National Standard for Information Systems–Bar Code Print Quality–Guideline (ANSI X3.182-1990).
- American National Standards Institute, 1430 Broadway, New York, NY 10018.
- Uniform Symbology Specification: Code 128. AIM USA, 634 Alpha Drive, Pittsburgh, PA 15238.
- Guideline for the Uniform Labeling of Blood and Blood Components. Published by the Food and Drug Administration, Center for Drugs and Biologics, Office of Biologics Research and Review, in cooperation with the American Blood Commission, August 1985.
- Guidelines for the Uniform Labeling of Blood and Blood Components (Draft: August, 1989). Prepared by American Association of Blood Banks, American Red Cross & Council of Community Blood Centers in cooperation with American Blood Commission & Food and Drug Administration Center for Biologics Evaluation and Research. Printed by Computype, Inc., St. Paul, Minnesota.