ISBT Code-128 An Introduction



The Blood Center New Orleans, LA FDA Registration Number 2374536 US License Number 0354

PROPERLY IDENTIFY INTENDED RECIPIENT See Circular of information for indications, contraindications, cautions and methods of infusion. This product may transmit infectious agents. Rx ONLY.

VOLUNTEER DONOR



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED

From 500 mL CPD Whole Blood. Store at 1 to 6°C.





12359 14 MAR 2008

What is ISBT Code-128?

It is a new, internationally recognized, method of labeling donated blood products, tissues, bone, and stem cells.
The Blood Center, as well as most other blood centers in the U.S. currently use Codabar labeling.

Why was ISBT Code-128 Developed?

Already in use in Europe for many years.

Ouring the first Gulf War, blood collected at blood centers in the U.S. and shipped to the military had the following problems:

- Same unit number used by multiple centers.
- Product information was not always uniform.

Why the Change Now?

 The American Association of Blood Banks (AABB), the major accreditation agency of blood centers in the U.S., made it a requirement for all centers to implement ISBT Code-128 symbology by May 1, 2008.
 The Blood Center has chosen to implement sooner on April 14, 2008. What Are the Benefits of ISBT Code-128 over Codabar?

International

- Language independent
- Provides a standard layout
- Capable of encoding an expanded data file in the label

What Are the Benefits of ISBT Code-128 over Codabar?

- Better accuracy
 - Codabar can have reproducible barcode
 - misreads
 - ISBT Code-128 has
 - Check digit built into the barcode
 - 3 self-checking features/characters

What Are the Benefits of ISBT 128 over Codabar?

Better traceability – Unit ID includes

- Facility identification
- Year of donation
- Donation sequence number
- Allows concatenation, or the scanning of two pieces of barcoded information at the same time.

Current Codabar Labeling

AS-1 RED BLOOD CELLS ADENINE-SALINE ADDED

16.9 mEq Sodium Added From 500 mL CPD Whole Blood Store at 1 to 6 C.

Collection Date

ded ₀₄₂₁₀

See circular of information for indications, contraindications, cautions and methods of infusion.

VOLUNTEER DONOR This product may transmit infectious agents. Rx only

PROPERLY IDENTIFY INTENDED RECIPIENT

Baxter Healthcare Corporation Fenwal Division Deerfield, IL 60015 USA 07-17-25-629

PL 146 Plastic

Rh POSITIVE Collected and Processed by THE BLOOD CENTER 312 South Galvez St. New Orleans, LA 70119 U.S. License No. 0354

EXPIRES 06/05/07

Registration # 2374536

CODE 4R3468 LOT M06K28011



14 MAR 2008

E0316V00

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

From 500 mL CPD Whole Blood Store at 1 to 6°C.

Donation Identification Number (or Unit Number) – Quadrant 1

$= \alpha p p p p y y n n n n n r K$

=	Data identifier -Tells the computer that this is a unit number. (only appears when scanned).						
α	Country Code – The U.S. is "W" or "K".						
ppppp	Collection Facility -The Blood Center is "0671".						
уу	Collection Year – Last two-digits of the year the product was collected.						

Donation Identification Number (or Unit Number) – Quadrant 1

 $= \alpha p p p p y y n n n n n \pi K$

nnnnnDonation Sequence NumberffFlag Character – Not used in the
U.S. so it will always be "00".KCheck Digit – MUST be entered when
manually entering the Donation
Identification Number into a computer
system. Aids in reducing typographical
errors during manual entry.

Donation Identification Number (or Unit Number) – Quadrant 1

W0671 08 **123456** 8

W0671 08 123456 8

- If recording manually, digits 1-13 ("W0671 08 123876") MUST be recorded.
 - The last six digits ("123456") may be used by multiple facilities on multiple years.
 - If unit is imported from another blood center, last six digits could be the same as another unit collected by The Blood Center.
 - Only one unit in the world will have the entire 13-digit number.

W0671 08 123456 8 8

- If typing manually into a computer, digits 1-13 must be entered PLUS the Check Digit 8
- If scanning into a computer via a barcode scanner, the characters "=" and "00" will appear before and after the 13-digits during the scan.
 - Your computer system may delete these extra characters. This is acceptable.

Product Code – Quadrant 2

- Describes products in terms of component classes, modifiers, attributes
 - Class: Red Cells, Platelets, Plasma (anticoagulant & additive, storage conditions)
 - Modifiers: Washed, Frozen, Thawed, Rejuvenated
 - Attributes: Irradiated, Leukocyte-reduced, Open vs. Closed system, Divided

Product Code – Quadrant 2

=<aoootds

Data identifier-Tells the computer that this is a product code (only appears when scanned).

α**0000 Product Description Code**

= <

ds

Type of Donation-Allogenic, Autologous Directed, etc.

Divisions/splits-If product is an aliquot from an original product (ex. "pedi-units")

Product Code – Quadrant 2 Donation Types

Character	Type of Donation					
0 (zero)	Not specified (null value)					
V	Volunteer homologous (allogeneic) donor (default)					
R	Volunteer research donor					
S	Volunteer source donor					
Т	Volunteer therapeutic collection					
Р	Paid homologous (allogeneic) collection					
r	Paid research collection					
S	Paid source collection					
А	Autologous collection, eligible for crossover					
1 (one)	For autologous use only					
Х	For autologous use only, biohazardous					
D	Volunteer directed collection, eligible for crossover					
d	Paid directed collection, eligible for crossover					
2	For directed recipient use only					
L	For directed recipient use only, limited exposure					
E	For directed recipient use only, medical exception					
Q	See (i.e., read [scan]) Special Testing bar code					
3	For directed recipient use only, biohazardous					
4	Designated collection					
5	Dedicated collection					

Product Code – Quadrant 2

E0316100 AUTOLOGOUS

RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED

From 500 mL CPD Whole Blood. Store at 1 to 6°C.

E0316 = Red Blood Cells produced from whole blood collected in a 500mL CPD anticoagulant collection bag with AS-1 added. Store refrigerated at 1° to 6°C.

1 = For autologous use only

OO = Not divided/Not split

- Digits 1-8 ("E0316100") should be used for manual recording.
- Manual entry into computer systems will vary depending upon the system.
- If scanning into a computer via a barcode scanner, the characters "=<" will appear before the eight-digits during the scan.
 - Your computer system may delete these extra characters. This is acceptable.
 - Scanning the information will be interpreted differently by computer systems.

If the unit was divided or split, the designations would be as follows:

 Divisions (designated as upper-case letters A-Z)

E03161A0 & E03161B0 – Unit divided into two

aliquots.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 125 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 125 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.

Splits (Designated as lower-case letters a-z) E03161Aa, E03161Ab, E03161Ba & E03161Bb Divisions "A" & "B" are split into two aliquots each.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 50 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 50 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 20 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.



RED BLOOD CELLS ADENINE – SALINE (AS – 1) ADDED DIVIDED

Approximately 20 mL. From 500 mL CPD Whole Blood. Store at 1 to 6°C.

Product Description Codes

Codabar

AS-1 RED BLOOD CELLS Adenine-Saline Added

ISBT 128 RED BLOOD CELLS ADENINE-SALINE (AS-1) ADDED

Product Description Codes

Codabar RED BLOOD CELLS DEGLYCEROLIZED

ISBT 128 DEGLYCEROLIZED RED BLOOD CELLS

	=% xxyy				
=%	Data identifier -Tells the computer that this is an ABO/Rh (only appears wher scanned).				
XX	ABO/Rh – Number indicated depends on				
	 Intended Use (Autologous, Directed) 				
	 Eligible for Cross Over 				
	Emergency ReleasedBiohazardous				

УУ

Other Phenotypes – Not used in the U.S.. Will always be "00".

Values for "xxyy"

Intended Use	O Pos	O Neg	A Pos	A Neg	B Pos	B Neg	AB Pos	AB Neg
Intended Use Not Specified	5100	9500	6200	0600	7300	1700	8400	2800
Autologous Use Only	5300	9700	6400	0800	7500	1900	8600	3000
Autologous Use Only/ Biohazardous	5400	9800	6500	0900	7600	2000	8700	3100
Directed, for crossover	5000	9400	6100	0500	7200	1600	8300	2700
Directed/Biohazardous	4900	9300	6000	0400	7100	1500	8200	2600
For Emergency Use Only	4800	9200	5900	0300	7000	1400	8100	2500

O positive (Not Specified)



Rh POSITIVE





FOR AUTOLOGOUS USE ONLY







BIOHAZARD For Autologous Use only

O positive (Directed, for Cross Over)







Expiration Date/Time Quadrant 4

&>cyyjjjhhmm

&> Data identifier-Tells the computer that this is an expiration date (only appears when scanned).
 Cyy Century and year Julian date (day of the year 000-365)

Expiration Date/Time Quadrant 4

&>cyyjjjhhmm

hhExpiration Time (Hours)- 00-23mmExpiration Time (Minutes)-00-60jjjJulian date (day of the year
000-365)

Expiration Date/Time Quadrant 4

Expiration Date 0080372359 06 FEB 2008

0080372359

The eye readable part of the label can also appear as:

06 FEB 2008 23:59

- *Note: The expiration time may not appear on the eyereadable part if the product expiration is day-dependent and not time-dependent.
- The eye readable expiration date/time can be used for manual recording.
- Manual entry into computer systems will vary depending upon the system.
- Scanning the information will be interpreted differently by computer systems.

Special Label – Quadrant 4

CMV Negative

Will appear below the expiration date



 Sickle Cell Negative, RBC Antibody ID Results and other special labels will NOT appear in this section. Implementation Steps for Non-Computerized Facilities

- Inform your administration about ISBT
- Revise forms for
 - 13 digit unit number
 - 8 digit product code
- Train nursing staff on labeling changes
 - Location of labeling items
 - Importance of recording all unit # & product code digits

Implementation Steps for Non-Computerized Facilities

- Inform all staff who work in blood bank about ISBT labeling
 - Location of labeling items
 - Importance of recording all 13 digits of unit number
 - Importance of recording all 8 digits of product code
- Register with ICCBBA
 - If you modify any products, including platelet pooling

Implementation Steps for Computerized Facilities

- All steps required for non-computerized facilities
- Verify that scanners can read both ISBT and Codabar
- Verify that other equipment can read ISBT labels on tubes
- Validate software upgrades that include ISBT

Implementation Steps for Computerized Facilities

- Obtain lists of ISBT product codes from blood suppliers
- Enter (or assure entrance of) ISBT product codes into computer
- Register with ICCBBA
 - If you modify any products, including platelet pooling
- Licensed facilities
 - Send in labels to FDA with form 2567 for approval
 - Send in any labeling variances

FOR MORE INFORMATION

Go to <u>www.thebloodcenter.org</u> and click "ISBT Info".

- Go to <u>www.iccbaa.org</u>.
- Go to www.aabb.org.

FOR MORE INFORMATION

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