

## Background Information Regarding the ISBT Label

### Useful References

1. [Guidance for Industry: Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels - 9/22/2006](#)
2. [United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128 - 9/22/2006](#)
3. [ISBT Label Checklist for Licensed Establishments](#)

In the following table, we are providing blood establishments with correct ISBT label information to expedite the review process where we anticipate potential errors in labeling submissions. Please use this table to make necessary corrections to labeling before submitting to CBER labeling for approval.

### Common Errors found in ISBT Label Submissions

Item	Incorrect	Correct	Guidance Document Reference Ref #1
Abbreviated legal name	Community Blood Bk of E. Anytown, Inc.	Community Blood Bank of East Anytown, Inc.	
Full legal name is not present on label	Blood Bank	Blood Bank, Inc.	Pg. 27
No license number on label		US License Number 9999	Pg. 27
Divided Units	Nothing present in code. For example: E4520V00	On divided units the code should have an A, B, or C indicating divided (E4520VA0) but additionally the term Divided should be on the label in the attribute line.	Pg. 18 - 19
Bacterial Monitoring	APHERESIS PLATELETS LEUKOCYTES REDUCED	Bacterial monitoring translates to 7d on the label APHERESIS PLATELETS – 7d LEUKOCYTES REDUCED	Pg. 75
Collection Date on products with no expiration date or Recovered Plasma	No collection date	The collection date goes in the upper left quadrant of the label if applicable	Pg. 28
Expiration Date and Time on products that are NOT time dependent	22 Jan 2005 2359	22 Jan 2005 Note: The hour should not be displayed if time >72 hours.	Pg. 15
Plasma Frozen ≤ 24 hours	Frozen within 24 hours of phlebotomy	Frozen within 24 hours after phlebotomy	Pg. 74-75
Donor Identification Number	Incorrect facility code used	Correct facility code	Pg. 27
Donor Identification Number	If firm uses “doing business as name” to	Facility code must match the legal name not dba	

	match the facility code	name	
Donor Identification Number	Font size and prominence are not the same throughout the entire number	Same font size throughout the entire number	Pg. 27
Rx Only	Rx Only. or Rx ONLY.	Rx Only	Pg. 27
	Rx ONLY or Rx only	Rx Only	Pg. 27
	RX ONLY	Rx Only	Pg. 27
Degree symbol in the temperature	1 – 6°C	1 – 6 C	Pg. 29
Periods after abbreviations	Approx. or mL.	Approx or mL	Pg. 51-53
Periods after temperature and anticoagulant statements	Store at 1 to 6 C. From 500 mL CPD Whole Blood.	Store at 1 to 6 C From 500 mL CPD Whole Blood	Pg. 51-53
Legal name in all capital letters	BLOOD BANK, INC.	Blood Bank, Inc.	Pg. 27
Firm's city in all capital letters	ANYTOWN	Anytown	Pg. 27
Hash marks through zeros	Ø	0	
Extra zeroes in numbers	023mL	23mL	
Autologous statement	for AUTOLOGOUS use only	FOR AUTOLOGOUS USE ONLY	Pg. 15, 30, 48
Biohazard statement in different font	BIOHAZARD FOR AUTOLOGOUS USE ONLY	BIOHAZARD FOR AUTOLOGOUS USE ONLY	Pg. 15, 30, 48
Caution statement in different font sizes or Circular of Information not capitalized	See circular of information for indications, contraindications, cautions and methods of infusion.	See Circular of Information for indications, contraindications, cautions and methods of infusion.	Pg. 27
Period after Properly Identify Intended Recipient	Properly Identify Intended Recipient.	Properly Identify Intended Recipient	Pg. 40
Lower Right Quadrant	Facility name, registration number and license number	This quadrant should be blank unless the firm has further manufacturing done by another facility then that facility information should be present	Pg. 31
Facility information in upper right quadrant	Collected and Processed by:	Nothing – remove statement	Pg. 27

**Optional Statements on Labels:**

Item	Comment	Guidance Document Reference, if applicable
Cryoprecipitate Labels	The standard does not address putting the statement “From 500 (or 450) mL Whole Blood” on the label but <b>this is acceptable if the code states it is from Whole Blood – code dependent</b>	Pg. 53 shows label without verbiage
Residual Leukocyte Count	The residual leukocyte count should be written with a superscript only. The firm may NOT use the carrot top with a regular 6 or the notation e in front of the 6. If printed, this should be below the storage temperature.	Pg. 73
mEq statement on Codabar labels for AS RBCs	This statement does NOT go on ISBT labels.	
Properly Identify Intended Recipient	This statement is approvable if it is in all capital letters as follows: PROPERLY IDENTIFY INTENDED RECIPIENT	
Facility Name and Address	It is approvable for the facility information to contain the street address, zip code or a phone number in the upper left quadrant. Per the guidance document only the city and state are required.	Pg. 28